trict of Columbia, Guam, the Commonwealth of the Northern Mariana Islands, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, and all other territories and possessions of the United States.

(5) Vessel

For the purposes of subsection (a) of this section, the term "vessel" does not include any ferry.

(Pub. L. 101-624, title XXV, § 2509, Nov. 28, 1990, 104 Stat. 4069; Pub. L. 101-508, title I, § 1203, Nov. 5, 1990, 104 Stat. 1388-11.)

REFERENCES IN TEXT

Section 101 of Public Law 92-73, referred to in subsec. (f)(1)(L), is listed in a Similar Provisions note set out under section 129 of this title.

CODIFICATION

Section is comprised of section 2509 of Pub. L. 101-624. Subsecs. (b) and (c)(2) of section 2509 of Pub. L. 101-624 amended section 147a(f) of Title 7, Agriculture, and section 114a of this title, respectively.

AMENDMENTS

1990—Subsec. (a)(1). Pub. L. 101-508, § 1203(1), substituted "an international passenger, commercial vessel, commercial aircraft, commercial truck, or railroad car," for "a commercial vessel, commercial aircraft, commercial truck, or railroad car,".

Subsec. (a)(3)(B)(ii). Pub. L. 101-508, § 1203(2)(A), inserted at end "Any such reimbursement shall be subject to appropriations under clause (v)."

Subsec. (a)(3)(B)(v). Pub. L. 101-508, § 1203(2)(B), added cl. (v).

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-508 effective Nov. 29, 1990, see section 1301 of Pub. L. 101-508, set out as a note under section 511r of Title 7, Agriculture.

CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

SUBCHAPTER IV—FOOD

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

SUBCHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

SUBCHAPTER VIII—IMPORTS AND EXPORTS

SUBCHAPTER IX—MISCELLANEOUS

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in sections 453, 457, 466, 467, 467f, 601, 607, 620, 679, 802, 811, 829, 902, 1033,

1049, 1052, 1401, 1402, 1403 of this title; title 7 sections 136v, 138i, 1431c, 5341, 6519; title 15 sections 70j, 1261, 1263, 1277, 1457, 1459, 1460, 2057a, 2057b, 2079; title 18 section 42; title 26 sections 170, 4817; title 35 sections 155, 156, 271; title 42 sections 262, 300aa-22, 300aa-23, 1396r-8, 1786, 3512, 7671.

SUBCHAPTER I—SHORT TITLE

§ 301. Short title

SHORT TITLE OF 1990 AMENDMENTS

Pub. L. 101-635, § 1(a), Nov. 28, 1990, 104 Stat. 4583, provided that: "This Act [enacting sections 379b to 379d and 394 of this title] may be cited as the 'Food and Drug Administration Revitalization Act'."

Pub. L. 101-629, § 1(a), Nov. 28, 1990, 104 Stat. 4511, provided that: "This Act [enacting sections 360*l* and 383 of this title, amending sections 321, 333, 351, 353, and 360c to 360j of this title and sections 263b to 263n of Title 42, The Public Health and Welfare, redesignating sections 263b to 263n of Title 42 as sections 360gg to 360ss of this title, repealing section 263b of Title 42, and enacting provisions set out as notes under sections 333, 360c, 360l, 360j, 360hh and 383 of this title] may be cited as the 'Safe Medical Devices Act of 1990'."

Pub. L. 101-535, § 1(a), Nov. 8, 1990, 104 Stat. 2353, provided that: "This Act [enacting section 343-1 of this title, amending sections 321, 337, 343, 345, and 371 of this title, and enacting provisions set out as notes under sections 343 and 343-1 of this title] may be cited as the 'Nutrition Labeling and Education Act of 1990'."

SHORT TITLE OF 1968 AMENDMENTS

Pub. L. 90-602, § 1, Oct. 18, 1968, 82 Stat. 1173, provided that: "This Act [enacting provisions now comprising part C (§§ 360gg-360ss) of subchapter III of this chapter and provisions set out as notes under section 360hh of this title] may be cited as the 'Radiation Control for Health and Safety Act of 1968'."

SUBCHAPTER II—DEFINITIONS

§ 321. Definitions; generally

For the purposes of this chapter—

[*See main edition for text of* (*a*) *to* (*f*)]

(g)(1) The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formularly, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clauses (A), (B), or (C) of this paragraph.

[*See main edition for text of* (*2*)]

(h) The term "device" (except when used in paragraph (n) of this section and in sections 331(i), 343(f), 352(c), and 362(c) of this title) means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

[*See main edition for text of* (*1*) *to* (*3*)]

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

[*See main edition for text of* (*i*) *to* (*aa*)]

(As amended Nov. 8, 1990, Pub. L. 101-535, § 5(b), 104 Stat. 2362; Nov. 28, 1990, Pub. L. 101-629, § 16(b), 104 Stat. 4526.)

AMENDMENT OF SUBSECTION (g)(1)

Pub. L. 101-535, §§ 5(b), 10(a), Nov. 8, 1990, 104 Stat. 2362, 2365, provided that, effective six months after the date of promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations, with certain exceptions, subsection (g)(1) of this section is amended by inserting at the end "A food for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug under clause (B) solely because the label or labeling contains such a claim."

AMENDMENTS

1990—Subsec. (g)(1). Pub. L. 101-629, § 16(b)(1), struck out before period at end "; but does not include devices or their components, parts, or accessories".

Subsec. (h). Pub. L. 101-629, § 16(b)(2), which directed the amendment of par. (3) by substituting "its primary" for "any of its principal", was executed by making the substitution in the concluding provisions of subsec. (h) to reflect the probable intent of Congress.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations, with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101-535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 346b, 350, 352, 355, 360b, 376, 802, 825 of this title; title 7 section 136; title 15 sections 1454, 1456, 1471, 2052, 2602; title 18 sections 842, 1365; title 35 section 156; title 42 sections 274e, 300cc-12, 1396r-8; title 49 App. section 2802.

SUBCHAPTER III—PROHIBITED ACTS AND PENALTIES

§ 331. Prohibited acts

The following acts and the causing thereof are prohibited:

[*See main edition for text of (a) to (d)*]

(e) The refusal to permit access to or copying of any record as required by section 350a or 373 of this title; or the failure to establish or maintain any record, or make any report, required under section 350a, 355(i) or (k), 357(d) or (g), 360b(j), (*l*), or (m), 360e(f), or 360i of this title, or the refusal to permit access to or verification or copying of any such required record.

[*See main edition for text of (f) to (i)*]

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this chapter, any information acquired under authority of section 344, 348, 350a, 355, 356, 357, 360, 360b, 360c, 360d, 360e, 360f, 360h, 360i, 360j, 374, 376, or 379 of this title concerning any method or process which as a trade secret is entitled to protection. This paragraph [1] does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee.

[*See main edition for text of (k) to (t)*]

(As amended Nov. 3, 1990, Pub. L. 101-502, § 5(j), 104 Stat. 1289; Nov. 5, 1990, Pub. L. 101-508, title IV, § 4755(c)(2), 104 Stat. 1388-210.)

AMENDMENTS

1990—Subsec. (e). Pub. L. 101-502 substituted "or (k)" for "or (j)".

Subsec. (j). Pub. L. 101-508 inserted at end "This paragraph does not authorize the withholding of information from either House of Congress or from, to the extent of matter within its jurisdiction, any committee or subcommittee of such committee or any joint committee of Congress or any subcommittee of such joint committee."

EFFECTIVE DATE OF 1990 AMENDMENT

Section 4755(c)(2) of Pub. L. 101-508 provided that the amendment made by that section is effective as if included in subtitle D of title VI of the Omnibus Budget Reconciliation Act of 1989, Pub. L. 101-239, title VI, §§ 6601, 6602, Dec. 19, 1989, 103 Stat. 2285, see 42 U.S.C. 300aa-1 note, 300aa-10 note.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 332, 333, 347b, 360i, 360j of this title; title 15 section 1456; title 42 section 1396r-8.

§ 332. Injunction proceedings

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 334, 360j of this title; title 15 section 1456; title 42 section 1396r-8.

[1] So in original. Probably should be "subsection".

§ 333. Penalties

[*See main edition for text of (a) to (d)*]

(e) Prohibited distribution of human growth hormone

(1) Except as provided in paragraph (2), whoever knowingly distributes, or possesses with intent to distribute, human growth hormone for any use in humans other than the treatment of a disease or other recognized medical condition, where such use has been authorized by the Secretary of Health and Human Services under section 355 of this title and pursuant to the order of a physician, is guilty of an offense punishable by not more than 5 years in prison, such fines as are authorized by title 18, or both.

(2) Whoever commits any offense set forth in paragraph (1) and such offense involves an individual under 18 years of age is punishable by not more than 10 years imprisonment, such fines as are authorized by title 18, or both.

(3) Any conviction for a violation of paragraphs (1) and (2) of this subsection shall be considered a felony violation of the Controlled Substances Act [21 U.S.C. 801 et seq.] for the purposes of forfeiture under section 413 of such Act [21 U.S.C. 853].

(4) As used in this subsection the term "human growth hormone" means somatrem, somatropin, or an analogue of either of them.

(5) The Drug Enforcement Administration is authorized to investigate offenses punishable by this subsection.

(f) Violations related to devices

(1)(A) Except as provided in subparagraph (B), any person who violates a requirement of this chapter which relates to devices shall be liable to the United States for a civil penalty in an amount not to exceed $15,000 for each such violation, and not to exceed $1,000,000 for all such violations adjudicated in a single proceeding.

(B) Subparagraph (A) shall not apply—

(i) to any person who violates the requirements of section 360i(a) or 360j(f) of this title unless such violation constitutes (I) a significant or knowing departure from such requirements, or (II) a risk to public health,

(ii) to any person who commits minor violations of section 360i(e) or 360i(f) of this title (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

(iii) to violations of section 351(a)(2)(A) of this title which involve one or more devices which are not defective.

(2)(A) A civil penalty under paragraph (1) shall be assessed by the Secretary by an order made on the record after opportunity for a hearing provided in accordance with this subparagraph and section 554 of title 5. Before issuing such an order, the Secretary shall give written notice to the person to be assessed a civil penalty under such order of the Secretary's proposal to issue such order and provide such person an opportunity for a hearing on the order. In the course of any investigation, the Secretary may issue subpoenas requiring the attendance and testimony of witnesses and

the production of evidence that relates to the matter under investigation.

(B) In determining the amount of a civil penalty, the Secretary shall take into account the nature, circumstances, extent, and gravity of the violation or violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and such other matters as justice may require.

(C) The Secretary may compromise, modify, or remit, with or without conditions, any civil penalty which may be assessed under paragraph (1). The amount of such penalty, when finally determined, or the amount agreed upon in compromise, may be deducted from any sums owing by the United States to the person charged.

(3) Any person who requested, in accordance with paragraph (2)(A), a hearing respecting the assessment of a civil penalty and who is aggrieved by an order assessing a civil penalty may file a petition for judicial review of such order with the United States Court of Appeals for the District of Columbia Circuit or for any other circuit in which such person resides or transacts business. Such a petition may only be filed within the 60-day period beginning on the date the order making such assessment was issued.

(4) If any person falls to pay an assessment of a civil penalty—

(A) after the order making the assessment becomes final, and if such person does not file a petition for judicial review of the order in accordance with paragraph (3), or

(B) after a court in an action brought under paragraph (3) has entered a final judgment in favor of the Secretary,

the Attorney General shall recover the amount assessed (plus interest at currently prevailing rates from the date of the expiration of the 60-day period referred to in paragraph (3) or the date of such final judgment, as the case may be) in an action brought in any appropriate district court of the United States. In such an action, the validity, amount, and appropriateness of such penalty shall not be subject to review.

(As amended Nov. 28, 1990, Pub. L. 101-629, § 17(a), 104 Stat. 4526; Nov. 29, 1990, Pub. L. 101-647, title XIX, § 1904, 104 Stat. 4853.)

REFERENCES IN TEXT

The Controlled Substances Act, referred to in subsec. (e)(3), is title II of Pub. L. 91-513, Oct. 27, 1970, 84 Stat. 1242, as amended, which is classified principally to subchapter I (§ 801 et seq.) of chapter 13 of this title. For complete classification of this Act to the Code, see Short Title note set out under section 801 of this title and Tables.

AMENDMENTS

1990—Subsec. (e). Pub. L. 101-647, § 1904, which directed the amendment of this section by "inserting a new subsection (e) as follows:" was executed by inserting the new subsec. (e) in place of the existing subsec. (e) to reflect the probable intent of Congress. A predecessor bill [H.R. 5269, § 303] which directed the amendment of subsec. (e) by substituting "human growth hormone" for "anabolic steroid" and defining "human growth hormone" was replaced by section 1904 of S. 3266 which became section 1904 of Pub. L. 101-647, which made similar changes, and in addition increased the terms of imprisonment, authorized the DEA to investigate punishable offenses, and incorporated the provisions of section 333a of this title [repealed by section 1905 of Pub. L. 101-647] which related to forfeiture of property for convictions in violation of subsec. (e) of this section. Prior to amendment, subsec. (e) read as follows:

"(1) Except as provided in paragraph (2), any person who distributes or possesses with the intent to distribute any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than three years or fined under title 18, or both.

"(2) Any person who distributes or possesses with the intent to distribute to an individual under 18 years of age, any anabolic steroid for any use in humans other than the treatment of disease pursuant to the order of a physician shall be imprisoned for not more than six years or fined under title 18, or both."

Subsec. (f). Pub. L. 101-629 added subsec. (f).

EFFECTIVE DATE OF 1990 AMENDMENT

Section 17(b) of Pub. L. 101-629 provided that:

"(b) EFFECTIVE DATE OF APPLICATION TO DEVICE USER FACILITIES.—

"(1) The Secretary of Health and Human Services shall conduct a study to determine whether there has been substantial compliance with the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)] by device user facilities (as defined in section 519(b)(5)(A) of such Act). The Secretary shall report the results of the study to the Congress after the expiration of 45 months after the date of the enactment of this Act [Nov. 28, 1990].

"(2)(A) If upon the expiration of 48 months after the date of the enactment of this Act the Secretary has not made the report required by paragraph (1), section 303(f) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 333(f)], as added by the amendment made by subsection (a), shall take effect with respect to device user facilities (as defined in section 519(b)(5)(A) of such Act).

"(B) If in the report under paragraph (1) the Secretary reports that there has been substantial compliance with the requirements of such section 519(b) by a type of device user facility and if the Secretary does not make a determination under subparagraph (C) with respect to such type of facility, such section 303(f) shall not take effect with respect to such type of facility.

"(C) If the Secretary determines in the report under paragraph (1) that there is not substantial compliance with the requirements of such section 519(b) by a type of device user facility or if the Secretary makes such a determination after making the report under paragraph (1), such section 303(f) shall take effect with respect to such type of facility upon the effective date of the report."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 346a, 360j, 859 of this title; title 15 section 1456.

§ 333a. Repealed. Pub. L. 101-647, title XIX, § 1905, Nov. 29, 1990, 104 Stat. 4853

Section, Pub. L. 100-690, title II, § 2401, Nov. 18, 1988, 102 Stat. 4230, related to forfeiture and illegal trafficking in steroids or human growth hormones.

§ 334. Seizure

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 360j, 372 of this title; title 15 section 1456; title 42 section 1396r-8.

§ 337. Proceedings in name of United States; provision as to subpoenas

[See main edition for text]

(As amended Nov. 8, 1990, Pub. L. 101-535, § 4, 104 Stat. 2362.)

AMENDMENT OF SECTION

Pub. L. 101-535, §§ 4, 10(a)(1)(C), Nov. 8, 1990, 104 Stat. 2362, 2365, provided that, effective 24 months after Nov. 8, 1990, this section is amended by substituting "(a) Except as provided in subsection (b) of this section, all such proceedings" for "All such proceedings" and "any proceeding under this section" for "any such proceeding" and by adding at the end the following:

(b)(1) A State may bring in its own name and within its jurisdiction proceedings for the civil enforcement, or to restrain violations, of section 341, 343(b), 343(c), 343(d), 343(e), 343(f), 343(g), 343(h), 343(i), 343(k), 343(q), or 343(r) of this title if the food that is the subject of the proceedings is located in the State.

(2) No proceeding may be commenced by a State under paragraph (1)—

(A) before 30 days after the State has given notice to the Secretary that the State intends to bring such proceeding,

(B) before 90 days after the State has given notice to the Secretary of such intent if the Secretary has, within such 30 days, commenced an informal or formal enforcement action pertaining to the food which would be the subject of such proceeding, or

(C) if the Secretary is diligently prosecuting a proceeding in court pertaining to such food, has settled such proceeding, or has settled the informal or formal enforcement action pertaining to such food.

In any court proceeding described in subparagraph (C), a State may intervene as a matter of right.

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective 24 months after Nov. 8, 1990, see section 10(a)(1)(C) of Pub. L. 101-535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

SUBCHAPTER IV—FOOD

§ 341. Definitions and standards for food

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 337, 343, 343-1, 350, 371 of this title.

§ 343. Misbranded food

A food shall be deemed to be misbranded—

[See main edition for text of (a) to (h)]

(i) Label where no representation as to definition and standard of identity

Unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food; except that spices, flavorings, and colors not required to be certified under section 376(c) of this title, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided,* That, to the extent that compliance with the requirements of clause (2) of this subsection is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

[See main edition for text of (j) to (p)]

(q) Nutrition information

(1) Except as provided in paragraphs (3), (4), and (5), if it is a food intended for human consumption and is offered for sale, unless its label or labeling bears nutrition information that provides—

(A)(i) the serving size which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food, or

(ii) if the use of the food is not typically expressed in a serving size, the common household unit of measure that expresses the serving size of the food,

(B) the number of servings or other units of measure per container,

(C) the total number of calories—

(i) derived from any source, and

(ii) derived from the total fat,

in each serving size or other unit of measure of the food,

(D) the amount of the following nutrients: Total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein contained in each serving size or other unit of measure,

(E) any vitamin, mineral, or other nutrient required to be placed on the label and labeling of food under this chapter before October 1, 1990, if the Secretary determines that such information will assist consumers in maintaining healthy dietary practices.

The Secretary may by regulation require any information required to be placed on the label or labeling by this paragraph or paragraph (2)(A) to be highlighted on the label or labeling by larger type, bold type, or contrasting color if the Secretary determines that such highlighting will assist consumers in maintaining healthy dietary practices.

(2)(A) If the Secretary determines that a nutrient other than a nutrient required by paragraph (1)(C), (1)(D), or (1)(E) should be included in the label or labeling of food subject to paragraph (1) for purposes of providing information regarding the nutritional value of such food that will assist consumers in maintaining healthy dietary practices, the Secretary may by regulation require that information relating to such additional nutrient be included in the label or labeling of such food.

(B) If the Secretary determines that the information relating to a nutrient required by paragraph (1)(C), (1)(D), or (1)(E) or subparagraph (A) of this paragraph to be included in the label or labeling of food is not necessary to assist consumers in maintaining healthy dietary practices, the Secretary may by regulation remove information relating to such nutrient from such requirement.

(3) For food that is received in bulk containers at a retail establishment, the Secretary may, by regulation, provide that the nutrition information required by paragraphs (1) and (2) be displayed at the location in the retail establishment at which the food is offered for sale.

(4)(A) The Secretary shall provide for furnishing the nutrition information required by paragraphs (1) and (2) with respect to raw agricultural commodities and raw fish by issuing voluntary nutrition guidelines, as provided by subparagraph (B) or by issuing regulations that are mandatory as provided by subparagraph (C).

(B)(i) Upon the expiration of 12 months after November 8, 1990, the Secretary, after providing an opportunity for comment, shall issue guidelines for food retailers offering raw agricultural commodities or raw fish to provide nutrition information specified in paragraphs (1) and (2). Such guidelines shall take into account the actions taken by food retailers during such 12-month period to provide to consumers nutrition information on raw agricultural commodities and raw fish. Such guidelines shall only apply—

(I) in the case of raw agricultural commodities, to the 20 varieties of vegetables most frequently consumed during a year and the 20 varieties of fruit most frequently consumed during a year, and

(II) to the 20 varieties of raw fish most frequently consumed during a year.

The vegetables, fruits, and raw fish to which such guidelines apply shall be determined by the Secretary by regulation and the Secretary may apply such guidelines regionally.

(ii) Upon the expiration of 12 months after November 8, 1990, the Secretary shall issue a final regulation defining the circumstances that constitute substantial compliance by food retailers with the guidelines issued under clause (i). The regulation shall provide that there is not substantial compliance if a significant number of retailers have failed to comply with the guidelines. The size of the retailers and the portion of the market served by retailers in compliance with the guidelines shall be considered in determining whether the substantial-compliance standard has been met.

(C)(i) Upon the expiration of 30 months after November 8, 1990, the Secretary shall issue a report on actions taken by food retailers to provide consumers with nutrition information for raw agricultural commodities and raw fish under the guidelines issued under subparagraph (A). Such report shall include a determination of whether there is substantial compliance with the guidelines.

(ii) If the Secretary finds that there is substantial compliance with the guidelines, the Secretary shall issue a report and make a determination of the type required in clause (i) every two years.

(D)(i) If the Secretary determines that there is not substantial compliance with the guidelines issued under subparagraph (A), the Secretary shall at the time such determination is made issue proposed regulations requiring that any person who offers raw agricultural commodities or raw fish to consumers provide, in a manner prescribed by regulations, the nutrition information required by paragraphs (1) and (2). The Secretary shall issue final regulations imposing such requirements 6 months after issuing the proposed regulations. The final regulations shall become effective 6 months after the date of their promulgation.

(ii) Regulations issued under clause (i) may require that the nutrition information required by paragraphs (1) and (2) be provided for more than 20 varieties of vegetables, 20 varieties of fruit, and 20 varieties of fish most frequently consumed during a year if the Secretary finds that a larger number of such products are frequently consumed. Such regulations shall permit such information to be provided in a single location in each area in which raw agricultural commodities and raw fish are offered for sale. Such regulations may provide that information shall be expressed as an average or range per serving of the same type of raw agricultural commodity or raw fish. The Secretary shall develop and make available to the persons who offer such food to consumers the information required by paragraphs (1) and (2).

(iii) Regulations issued under clause (i) shall permit the required information to be provided in each area of an establishment in which raw agricultural commodities and raw fish are offered for sale. The regulations shall permit food retailers to display the required information by supplying copies of the information provided by the Secretary, by making the information available in brochure, notebook or leaflet form, or by posting a sign disclosing the information. Such regulations shall also permit presentation of the required information to be supplemented by a video, live demonstration, or other media which the Secretary approves.

(E) For purposes of this paragraph, the term "fish" includes freshwater or marine fin fish, crustaceans, and mollusks, including shellfish,

amphibians, and other forms of aquatic animal life.

(F) No person who offers raw agricultural commodities or raw fish to consumers may be prosecuted for minor violations of this paragraph if there has been substantial compliance with the requirements of this subsection.

(5)(A) Paragraphs (1), (2), (3), and (4) shall not apply to food—

(i) which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in clause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

(iii) which is an infant formula subject to section 350a of this title,

(iv) which is a medical food as defined in section 360ee(b) of this title, or

(v) which is described in section 345(2) of this title.

(B) Paragraphs (1) and (2) shall not apply to the label of a food if the Secretary determines by regulations that compliance with such paragraphs is impracticable because the package of such food is too small to comply with the requirements of such paragraphs and if the label of such food does not contain any nutrition information.

(C) If a food contains insignificant amounts, as determined by the Secretary, of all the nutrients required by paragraphs (1) and (2) to be listed in the label or labeling of food, the requirements of such paragraphs shall not apply to such food if the label, labeling, or advertising of such food does not make any claim with respect to the nutritional value of such food. If a food contains insignificant amounts, as determined by the Secretary, of more than one-half the nutrients required by paragraphs (1) and (2) to be in the label or labeling of the food, the Secretary shall require the amounts of such nutrients to be stated in a simplified form prescribed by the Secretary.

(D) If a person offers food for sale and has annual gross sales made or business done in sales to consumers which is not more than $500,000 or has annual gross sales made or business done in sales of food to consumers which is not more than $50,000, the requirements of paragraphs (1), (2), (3), and (4) shall not apply with respect to food sold by such person to consumers unless the label or labeling of food offered by such person provides nutrition information or makes a nutrition claim.

(E) If a food to which section 350 of this title applies (as defined in section 350(c) of this title) contains one or more of the nutrients required by paragraph (1) or (2) to be in the label or labeling of the food, the label or labeling of such food shall comply with the requirements of paragraphs (1) and (2) in a manner which is appropriate for such food and which is specified in regulations of the Secretary.

(F) Paragraphs (1), (2), (3), and (4) shall not apply to food which is sold by a food distributor if the food distributor principally sells food to restaurants or other establishments in which food is served for immediate human consumption and does not manufacture, process, or repackage the food it sells.

(r) Nutrition levels and health-related claims

(1) Except as provided in subparagraphs (A) through (C) of paragraph (5), if it is a food intended for human consumption which is offered for sale and for which a claim is made in the label or labeling of the food which expressly or by implication—

(A) characterizes the level of any nutrient which is of the type required by subsection (q)(1) or (q)(2) of this section to be in the label or labeling of the food unless the claim is made in accordance with paragraph (2), or

(B) characterizes the relationship of any nutrient which is of the type required by subsection (q)(1) or (q)(2) of this section to be in the label or labeling of the food to a disease or a health-related condition unless the claim is made in accordance with paragraph (3) or 5(D).[1]

A statement of the type required by subsection (q) of this section that appears as part of the nutrition information required or permitted by such subsection is not a claim which is subject to this subsection and a claim subject to subparagraph (A) is not subject to subparagraph (B).

(2)(A) Except as provided in paragraphs (4)(A)(ii) and (4)(A)(iii) and subparagraphs (A) through (C) of paragraph (5), a claim described in paragraph (1)(A)—

(i) may be made only if the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary,

(ii) may not state the absence of a nutrient unless—

(I) the nutrient is usually present in the food or in a food which substitutes for the food as defined by the Secretary by regulation, or

(II) the Secretary by regulation permits such a statement on the basis of a finding that such a statement would assist consumers in maintaining healthy dietary practices and the statement discloses that the nutrient is not usually present in the food,

(iii) may not be made with respect to the level of cholesterol in the food if the food contains, as determined by the Secretary by regulation, fat or saturated fat in an amount which increases to persons in the general population the risk of disease or a health related condition which is diet related unless—

(I) the Secretary finds by regulation that the level of cholesterol is substantially less than the level usually present in the food or in a food which substitutes for the food and which has a significant market share, or the Secretary by regulation permits a statement

[1] So in original. Probably should be "(5)(D)."

regarding the absence of cholesterol on the basis of a finding that cholesterol is not usually present in the food and that such a statement would assist consumers in maintaining healthy dietary practices and the regulation requires that the statement disclose that cholesterol is not usually present in the food, and

(II) the label or labeling of the food discloses the level of such fat or saturated fat in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of cholesterol,

(iv) may not be made with respect to the level of saturated fat in the food if the food contains cholesterol unless the label or labeling of the food discloses the level of cholesterol in the food in immediate proximity to such claim and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of saturated fat,

(v) may not state that a food is high in dietary fiber unless the food is low in total fat as defined by the Secretary or the label or labeling discloses the level of total fat in the food in immediate proximity to such statement and with appropriate prominence which shall be no less than one-half the size of the claim with respect to the level of dietary fiber, and

(vi) may not be made if the Secretary by regulation prohibits the claim because the claim is misleading in light of the level of another nutrient in the food.

(B) If a claim described in paragraph (1)(A) is made with respect to a nutrient in a food, the label or labeling of such food shall contain, prominently and in immediate proximity to such claim, the following statement: "See _____ for nutrition information.". In the statement—

(i) the blank shall identify the panel on which the information described in the statement may be found, and

(ii) if the Secretary determines that the food contains a nutrient at a level which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, the statement shall also identify such nutrient.

(C) Paragraph (2)(A) does not apply to a claim described in paragraph (1)(A) and contained in the label or labeling of a food if such claim is contained in the brand name of such food and such brand name was in use on such food before October 25, 1989, unless the brand name contains a term defined by the Secretary under paragraph (2)(A)(i). Such a claim is subject to subsection (a) of this section.

(D) Paragraph (2) does not apply to a claim described in paragraph (1)(A) which uses the term "diet" and is contained in the label or labeling of a soft drink if (i) such claim is contained in the brand name of such soft drink, (ii) such brand name was in use on such soft drink before October 25, 1989, and (iii) the use of the term "diet" was in conformity with section 105.66 of title 21 of the Code of Federal Regulations. Such a claim is subject to subsection (a) of this section.

(E) Clauses (i) through (v) of paragraph (2)(A) do not apply to a statement in the label or labeling of food which describes the percentage of vitamins and minerals in the food in relation to the amount of such vitamins and minerals recommended for daily consumption by the Secretary.

(3)(A) Except as provided in paragraph (5), a claim described in paragraph (1)(B) may only be made—

(i) if the claim meets the requirements of the regulations of the Secretary promulgated under subparagraph (B), and

(ii) if the food for which the claim is made does not contain, as determined by the Secretary by regulation, any nutrient in an amount which increases to persons in the general population the risk of a disease or health-related condition which is diet related, taking into account the significance of the food in the total daily diet, except that the Secretary may by regulation permit such a claim based on a finding that such a claim would assist consumers in maintaining healthy dietary practices and based on a requirement that the label contain a disclosure of the type required by paragraph (2)(B).

(B)(i) The Secretary shall promulgate regulations authorizing claims of the type described in paragraph (1)(B) only if the Secretary determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recoguized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence.

(ii) A regulation described in clause (i) shall describe—

(I) the relationship between a nutrient of the type required in the label or labeling of food by subsection (q)(1) or (q)(2) of this section and a disease or health-related condition, and

(II) the significance of each such nutrient in affecting such disease or health-related condition.

(iii) A regulation described in clause (i) shall require such claim to be stated in a manner so that the claim is an accurate representation of the matters set out in clause (ii) and so that the claim enables the public to comprehend the information provided in the claim and to understand the relative significance of such information in the context of a total daily diet.

(4)(A)(i) Any person may petition the Secretary to issue a regulation under paragraph (2)(A)(i) or (3)(B) relating to a claim described in paragraph (1)(A) or (1)(B). Not later than 100 days after the petition is received by the Secretary, the Secretary shall issue a final decision denying the petition or file the petition for further action by the Secretary. If the Secretary denies the petition, the petition shall not

be made available to the public. If the Secretary files the petition, the Secretary shall deny the petition or issue a proposed regulation to take the action requested in the petition not later than 90 days after the date of such decision.

(ii) Any person may petition the Secretary for permission to use in a claim described in paragraph (1)(A) terms that are consistent with the terms defined by the Secretary under paragraph (2)(A)(i). Within 90 days of the submission of such a petition, the Secretary shall issue a final decision denying the petition or granting such permission.

(iii) Any person may petition the Secretary for permission to use an implied claim described in paragraph (1)(A) in a brand name. After publishing notice of an opportunity to comment on the petition in the Federal Register and making the petition available to the public, the Secretary shall grant the petition if the Secretary finds that such claim is not misleading and is consistent with terms defined by the Secretary under paragraph (2)(A)(i). The Secretary shall grant or deny the petition within 100 days of the date it is submitted to the Secretary and the petition shall be considered granted if the Secretary does not act on it within such 100 days.

(B) A petition under subparagraph (A)(i) respecting a claim described in paragraph (1)(A) or (1)(B) shall include an explanation of the reasons why the claim meets the requirements of this subsection and a summary of the scientific data which supports such reasons.

(C) If a petition for a regulation under paragraph (3)(B) relies on a report from an authoritative scientific body of the United States, the Secretary shall consider such report and shall justify any decision rejecting the conclusions of such report.

(5)(A) This subsection does not apply to infant formulas subject to section 350a(h) of this title and medical foods as defined in section 360ee(b) of this title.

(B) Clauses (iii) through (v) of paragraph (2)(A) and paragraph (2)(B) do not apply to food which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.

(C) A paragraph (1)(A) claim made with respect to a food which claim is required by a standard of identity issued under section 341 of this title shall not be subject to paragraph (2)(A)(i) or (2)(B).

(D) A paragraph (1)(B) claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall not be subject to paragraph (3) but shall be subject to a procedure and standard, respecting the validity of such claim, established by regulation of the Secretary.

(As amended Nov. 8, 1990, Pub. L. 101-535, §§ 2(a), 3(a), 7, 104 Stat. 2353, 2357, 2364.)

AMENDMENTS

1990—Subsec. (i). Pub. L. 101-535, § 7, substituted "Unless" for "If it is not subject to the provisions of subsection (g) of this section unless", inserted "and if the food purports to be a beverage containing vegetable or fruit juice, a statement with appropriate prominence on the information panel of the total percentage of such fruit or vegetable juice contained in the food", and substituted "colors not required to be certified under section 376(c) of this title" for "colorings" the first time appearing.

Subsec. (q). Pub. L. 101-535, § 2(a), added subsec. (q).

Subsec. (r). Pub. L. 101-535, § 3(a), added subsec. (r).

EFFECTIVE DATE OF 1990 AMENDMENT

Section 10(a) of Pub. L. 101-535 provided that:

"(1) Except as provided in paragraph (2)—

"(A) the amendments made by section 2 [amending this section] shall take effect 6 months after—

"(i) the date of the promulgation of all final regulations required to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act [subsec. (q) of this section], or

"(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations,

except that section 403(q)(4) of such Act shall take effect as prescribed by such section,

"(B) the amendments made by section 3 [amending this section] shall take effect 6 months after—

"(i) the date of the promulgation of final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act, or

"(ii) if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations, except that any person marketing a food the brand name of which contains a term defined by the Secretary under section 403(r)(2)(A)(i) of the Federal Food, Drug, and Cosmetic Act shall be given an additional 6 months to comply with section 3,

"(C) the amendments made by section 4 [amending section 337 of this title] shall take effect 24 months after the date of the enactment of this Act [Nov. 8, 1990], and

"(D) the amendments made by section 5 [amending sections 321 and 345 of this title] shall take effect on the date the amendments made by section 3 take effect.

"(2) Section 403(q) of the Federal Food, Drug, and Cosmetic Act (as added by section 2) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 2 and section 403(r) of the Federal Food, Drug, and Cosmetic Act (as added by section 3) shall not apply with respect to food which was labeled before the effective date of the amendments made by section 3.

"(3)(A) If the Secretary finds that a person who is subject to section 403(q)(4) of such Act is unable to comply with the requirements of such section upon the effective date of final regulations to implement section 403(q) of such Act or of proposed regulations to be considered as such final regulations because the Secretary has not made available to such person the information required by such section, the Secretary shall delay the application of such section to such person for such time as the Secretary may require to provide such information.

"(B) If the Secretary finds that compliance with section 403(q) or 403(r)(2) of such Act would cause an undue economic hardship, the Secretary may delay the application of such sections for no more than one year."

Section 10(c) of Pub. L. 101-535 provided that: "The amendments made by section 7 [amending this section] shall take effect one year after the date of the enactment of this Act [Nov. 8, 1990]."

REGULATIONS

Section 2(b) of Pub. L. 101-535 provided that:

"(1) The Secretary of Health and Human Services shall issue proposed regulations to implement section 403(q) of the Federal Food, Drug, and Cosmetic Act

[21 U.S.C. 343(q)] within 12 months after the date of the enactment of this Act [Nov. 8, 1990]. Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement the requirements of such section. Such regulations shall—

"(A) require the required information to be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and to understand its relative significance in the context of a total daily diet,

"(B) include regulations which establish standards, in accordance with paragraph (1)(A), to define serving size or other unit of measure for food,

"(C) permit the label or labeling of food to include nutrition information which is in addition to the information required by such section 403(q) and which is of the type described in subparagraph (1) or (2) of such section, and

"(D) permit the nutrition information on the label or labeling of a food to remain the same or permit the information to be stated as a range even though (i) there are minor variations in the nutritional value of the food which occur in the normal course of the production or processing of the food, or (ii) the food is comprised of an assortment of similar foods which have variations in nutritional value.

"(2) If the Secretary of Health and Human Services does not promulgate final regulations under paragraph (1) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1) shall be considered as the final regulations upon the expiration of such 24 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations.

"(3) If the Secretary of Health and Human Services does not promulgate final regulations under section 403(q)(4) of the Federal Food, Drug, and Cosmetic Act upon the expiration of 6 months after the date on which the Secretary makes a finding that there has been no substantial compliance with section 403(q)(4)(C) of such Act, the proposed regulations issued in accordance with such section shall be considered as the final regulations upon the expiration of such 6 months. There shall be promptly published in the Federal Register notice of new status of the proposed regulations."

Section 3(b) of Pub. L. 101-535 provided that:

"(1)(A) Within 12 months of the date of the enactment of this Act [Nov. 8, 1990], the Secretary of Health and Human Services shall issue proposed regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(r)]. Such regulations—

"(i) shall identify claims described in section 403(r)(1)(A) of such Act which comply with section 403(r)(2) of such Act,

"(ii) shall identify claims described in section 403(r)(1)(B) of such Act which comply with section 403(r)(3) of such Act,

"(iii) shall, in defining terms used to characterize the level of any nutrient in food under section 403(r)(2)(A)(i) of such Act, define—

"(I) free,

"(II) low,

"(III) light or lite,

"(IV) reduced,

"(V) less, and

"(VI) high,

unless the Secretary finds that the use of any such term would be misleading,

"(iv) shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in section 403(r)(2)(A)(i) of such Act,

"(v) shall provide that if multiple claims subject to section 403(r)(1)(A) of such Act are made on a single panel of the food label or page of a labeling brochure, a single statement may be made to satisfy section 403(r)(2)(B) of such Act,

"(vi) shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(3) of such Act: Calcium and osteoporosis, dietary fiber and cancer, lipids and cardiovascular disease, lipids and cancer, sodium and hypertension, and dietary fiber and cardiovascular disease,

"(vii) shall not require a person who proposes to make a claim described in section 403(r)(1)(B) of such Act which is in compliance with such regulations to secure the approval of the Secretary before making such claim,

"(viii) may permit a claim described in section 403(r)(1)(A) of such Act to be made for butter,

"(ix) may, in defining terms under section 403(r)(2)(A)(i), include similar terms which are commonly understood to have the same meaning, and

"(x) shall establish, as required by section 403(r)(5)(D), the procedure and standard respecting the validity of claims made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances and shall determine whether claims respecting the following nutrients and diseases meet the requirements of section 403(r)(5)(D) of such Act: folic acid and neural tube defects, antioxident vitamins and cancer, zinc and immune function in the elderly, and omega-3 fatty acids and heart disease.

"(B) Not later than 24 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement section 403(r) of the Federal Food, Drug, and Cosmetic Act.

"(2) If the Secretary does not promulgate final regulations under paragraph (1)(B) upon the expiration of 24 months after the date of the enactment of this Act, the proposed regulations issued in accordance with paragraph (1)(A) shall be considered as the final regulations upon the expiration of such 24 months. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations."

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Section 9 of Pub. L. 101-535 provided that: "The amendments made by this Act [enacting section 343-1 of this title and amending this section and sections 321, 337, 345, and 371 of this title] shall not be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 301 et seq.], the Federal Meat Inspection Act [21 U.S.C. 601 et seq.], the Poultry Products Inspection Act [21 U.S.C. 451 et seq.], and the Egg Products Inspection Act [21 U.S.C. 1031 et seq.]."

CONSUMER EDUCATION

Section 2(c) of Pub. L. 101-535 provided that: "The Secretary of Health and Human Services shall carry out activities which educate consumers about—

"(1) the availability of nutrition information in the label or labeling of food, and

"(2) the importance of that information in maintaining healthy dietary practices."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 337, 343-1, 345, 347, 350, 371 of this title.

§ 343-1. National uniform nutrition labeling

(a) Except as provided in subsection (b) of this section, no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce—

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not iden-

tical to such standard of identity or that is not identical to the requirement of section 343(g) of this title,

(2) any requirement for the labeling of food of the type required by section 343(c), 343(e), or 343(i)(2) of this title that is not identical to the requirement of such section,

(3) any requirement for the labeling of food of the type required by section 343(b), 343(d), 343(f), 343(h), 343(i)(1), or 343(k) of this title that is not identical to the requirement of such section,

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 343(q) of this title, except a requirement for nutrition labeling of food which is exempt under clause (i) or (ii) of section 343(q)(5)(A) of this title, or

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title made in the label or labeling of food that is not identical to the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food which is exempt under subparagraph (B) [1] of such section.

Paragraph (3) shall take effect in accordance with section 6(b) of the Nutrition Labeling and Education Act of 1990.

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a) of this section, under such conditions as may be prescribed by regulation, any State or local requirement that—

(1) would not cause any food to be in violation of any applicable requirement under Federal law,

(2) would not unduly burden interstate commerce, and

(3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) of this section.

(June 25, 1938, ch. 675, § 403A, as added Nov. 8, 1990, Pub. L. 101-535, § 6(a), 104 Stat. 2362.)

REFERENCES IN TEXT

Subparagraph (B) of such section, referred to in subsec. (a)(5), probably means subparagraph (B) of section 343(r)(5) of this title.

Section 6(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535], referred to in subsec. (a), is set out below.

EFFECTIVE DATE

Section 10(b) of Pub. L. 101-535 provided that:

"(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by section 6 [enacting this section] shall take effect—

"(A) with respect to a requirement of a State or political subdivision described in paragraph (1) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act [subsec. (a)(1) of this section], on the date of the enactment of this Act [Nov. 8, 1990],

"(B) with respect to a requirement of a State or political subdivision described in paragraph (2) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, one year after the date of the enactment of this Act,

"(C) with respect to a requirement of a State or political subdivision described in paragraph (3) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, as prescribed by section 6(b) of the Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535, set out below],

"(D) with respect to a requirement of a State or political subdivision described in paragraph (4) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(q) of such Act [21 U.S.C. 343(q)] take effect, and

"(E) with respect to a requirement of a State or political subdivision described in paragraph (5) of section 403A(a) of the Federal Food, Drug, and Cosmetic Act, on the date regulations to implement section 403(r) of such Act take effect.

"(2) EXCEPTION.—If a State or political subdivision submits a petition under section 403A(b) of the Federal Food, Drug, and Cosmetic Act for a requirement described in section 403A(a) of such Act within 18 months of the date of the enactment of this Act, paragraphs (3) through (5) of such section 403A(a) shall not apply with respect to such State or political subdivision requirement until—

"(1) 24 months after the date of the enactment of this Act, or

"(2) action on the petition,

whichever occurs later."

Section 6(b) of Pub. L. 101-535 provided that:

"(1) For the purpose of implementing section 403A(a)(3) [21 U.S.C. 343-1(a)(3)], the Secretary of Health and Human Services shall enter into a contract with a public or nonprofit private entity to conduct a study of—

"(A) State and local laws which require the labeling of food that is of the type required by sections 403(b), 403(d), 403(f), 403(h), 403(i)(1), and 403(k) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 343(b), (d), (f), (h), (i)(1), (k)], and

"(B) the sections of the Federal Food, Drug, and Cosmetic Act referred to in subparagraph (A) and the regulations issued by the Secretary to enforce such sections to determine whether such sections and regulations adequately implement the purposes of such sections.

"(2) The contract under paragraph (1) shall provide that the study required by such paragraph shall be completed within 6 months of the date of the enactment of this Act [Nov. 8, 1990].

"(3)(A) Within 9 months of the date of the enactment of this Act, the Secretary shall publish a proposed list of sections which are adequately being implemented by regulations as determined under paragraph (1)(B) and sections which are not adequately being implemented by regulations as so determined. After publication of the lists, the Secretary shall provide 60 days for comments on such lists.

"(B) Within 24 months of the date of the enactment of this Act, the Secretary shall publish a final list of sections which are adequately being implemented by regulations and a list of sections which are not adequately being implemented by regulations. With respect to a section which is found by the Secretary to be adequately implemented, no State or political subdivision of a State may establish or continue in effect as to any food in interstate commerce any requirement which is not identical to the requirement of such section.

"(C) Within 24 months of the date of the enactment of this Act, the Secretary shall publish proposed revisions to the regulations found to be inadequate under subparagraph (B) and within 30 months of such date shall issue final revisions. Upon the effective date of such final revisions, no State or political subdivision may establish or continue in effect any requirement which is not identical to the requirement of the section which had its regulations revised in accordance with this subparagraph.

"(D)(i) If the Secretary does not issue a final list in accordance with subparagraph (B), the proposed list

[1] See References in Text note below.

issued under subparagraph (A) shall be considered the final list and States and political subdivisions shall be preempted with respect to sections found to be adequate in such proposed list in accordance with subparagraph (B).

"(ii) If the Secretary does not issue final revisions of regulations in accordance with subparagraph (C), the proposed revisions issued under such subparagraph shall be considered the final revisions and States and political subdivisions shall be preempted with respect to sections the regulations of which are revised by the proposed revisions.

"(E) Subsection (b) of section 403A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the prohibition prescribed by subparagraphs (B) and (C)."

CONSTRUCTION OF PUB. L. 101-535

Section 6(c) of Pub. L. 101-535 provided that:

"(1) The Nutrition Labeling and Education Act of 1990 [Pub. L. 101-535, see Short Title of 1990 Amendment note set out under section 301 of this title] shall not be construed to preempt any provision of State law, unless such provision is expressly preempted under section 403A of the Federal Food, Drug, and Cosmetic Act [this section].

"(2) The amendment made by subsection (a) [enacting this section] and the provisions of subsection (b) [set out as a note above] shall not be construed to apply to any requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food.

"(3) The amendment made by subsection (a), the provisions of subsection (b) and paragraphs (1) and (2) of this subsection shall not be construed to affect preemption, express or implied, of any such requirement of a State or political subdivision, which may arise under the Constitution, any provision of the Federal Food, Drug, and Cosmetic Act [this chapter] not amended by subsection (a), any other Federal law, or any Federal regulation, order, or other final agency action reviewable under chapter 7 of title 5, United States Code."

Amendments by Pub. L. 101-535 not to be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

§ 345. Regulations making exemptions

[*See main edition for text*]

(As amended Nov. 8, 1990, Pub. L. 101-535, § 5(a), 104 Stat. 2362.)

AMENDMENT OF SECTION

Pub. L. 101-535, §§ 5(a), 10(a), Nov. 8, 1990, 104 Stat. 2362, 2365, provided that, effective six months after the date of promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations, with certain exceptions, this section is amended by inserting at the end "This section does not apply to the labeling requirements of sections 343(q) and 343(r) of this title."

EFFECTIVE DATE OF 1990 AMENDMENT

Amendment by Pub. L. 101-535 effective six months after the date of the promulgation of final regulations to implement section 343(r) of this title, or if such regulations are not promulgated, the date proposed regulations are to be considered as such final regulations, with exception for persons marketing food the brand name of which contains a term defined by the Secretary under section 343(r)(2)(A)(i) of this title, see section 10(a) of Pub. L. 101-535, set out as a note under section 343 of this title.

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter authority of Secretary of Health and Human Services and Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 343 of this title.

§ 346a. Tolerances for pesticide chemicals in or on raw agricultural commodities

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 342, 346b, 453, 601, 1033 of this title; title 7 section 450i.

§ 348. Food additives

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 331, 342, 376, 453, 601, 1033 of this title; title 7 section 450i; title 15 section 1262; title 35 section 155.

§ 350. Vitamins and minerals

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 343 of this title.

§ 350a. Infant formulas

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 343, 374 of this title.

SUBCHAPTER V—DRUGS AND DEVICES

PART A—DRUGS AND DEVICES

§ 351. Adulterated drugs and devices

A drug or device shall be deemed to be adulterated—

[*See main edition for text of (a) to (e)*]

(f) Certain class III devices

(1) If it is a class III device—

(A) [*See main edition for text of (i)*]

(ii) [*See main edition for text of (I)*]

(II) for which such an application was filed and approval of the application has been denied, suspended, or withdrawn, or such a notice was filed and has been declared not completed or the approval of the device under the protocol has been withdrawn;

(B) [*See main edition for text of (i)*]

(ii) which has an application which has been suspended or is otherwise not in effect; or

(C) which was classified under section 360j(l) of this title into class III, which under such section is required to have in effect an approved application under section 360e of this title, and which has an application which has been suspended or is otherwise not in effect.

[*See main edition for text of (2); (g) to (i)*]

(As amended Nov. 28, 1990, Pub. L. 101-629, § 9(b), 104 Stat. 4521.)

AMENDMENTS

1990—Subsec. (f)(1). Pub. L. 101-629, § 9(b), which directed the amendment of subpars. (A) to (C) of subsec. (f), was executed by making the amendments in subpars. (A) to (C) of par. (1) of subsec. (f) as follows to reflect the probable intent of Congress: in subpar. (A)(ii)(II), substituted ", suspended, or withdrawn" for "or withdrawn"; in subpar. (B)(ii), substituted "which has an application which has been suspended or is otherwise not in effect" for "which does not have such an application in effect"; and in subpar. (C), substituted "which has an application which has been suspended or is otherwise not in effect" for "which does not have such an application in effect".

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 333, 334, 356, 357, 360b, 360c, 360j, 371, 376, 382 of this title.

§ 352. Misbranded drugs and devices

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 321, 333, 334, 353, 357, 360, 360c, 360j, 371, 802 of this title; title 42 section 1396r-8.

§ 353. Exemptions and consideration for certain drugs, devices, and biological products

[*See main edition for text of (a) to (e), (c)*]

(f) Regulation of combination products

(1) The Secretary shall designate a component of the Food and Drug Administration to regulate products that constitute a combination of a drug, device, or biological product. The Secretary shall determine the primary mode of action of the combination product. If the Secretary determines that the primary mode of action is that of—

(A) a drug (other than a biological product), the persons charged with premarket review of drugs shall have primary jurisdiction,

(B) a device, the persons charged with premarket review of devices shall have primary jurisdiction, or

(C) a biological product, the persons charged with premarket review of biological products shall have primary jurisdiction.

(2) Nothing in this subsection shall prevent the Secretary from using any agency resources of the Food and Drug Administration necessary to ensure adequate review of the safety, effectiveness, or substantial equivalence of an article.

(3) The Secretary shall promulgate regulations to implement market approval procedures in accordance with paragraphs (1) and (2) not later than 1 year after November 28, 1990.

(4) As used in this subsection:

(A) The term "biological product" has the meaning given the term in section 262(a) of title 42.

(B) The term "market clearance" includes—

(i) approval of an application under section 355, 357, 360e, or 360j(g) of this title,

(ii) a finding of substantial equivalence under this part, and

(iii) approval of a product or establishment license under subsection (a) or (d) of section 262 of title 42.

(As amended Nov. 28, 1990, Pub. L. 101-629, § 16(a), 104 Stat. 4526.)

AMENDMENTS

1990—Pub. L. 101-629, § 16(a)(1), substituted "Exemptions and consideration for certain drugs, devices, and biological products" for "Exemptions in case of drugs and devices" in section catchline.

Subsec. (f). Pub. L. 101-629, § 16(a)(2), added subsec. (f).

§ 355. New drugs

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 334, 353, 357, 360, 360b, 360j, 360aa to 360ee, 374, 381, 382, 802, 811, 827 of this title; title 26 section 28; title 28 section 2201; title 35 sections 155A, 156, 271; title 42 sections 236, 300cc-12, 300cc-13, 300cc-17, 1395y, 1396r-8.

§ 356. Certification of drugs containing insulin

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 360 of this title; title 15 section 1459; title 42 section 1396r-8.

§ 357. Certification of drugs containing penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 353, 360, 360j, 360aa, 360bb, 360cc, 360ee, 374 of this title; title 26 section 28; title 35 section 156; title 42 section 1396r-8.

§ 360. Registration of producers of drugs or devices

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 352, 355, 360c, 360e, 360i, 360j, 381 of this title.

§ 360c. Classification of devices intended for human use

(a) Classes of devices

(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

[*See main edition for text of (i)*]

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

[*See main edition for text of (I) and (II)*]

is to be regulated by the controls referred to in clause (i).

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance, including the promulgation of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions in accordance with section 360(k) of this title), recommendations, and other appropriate actions as the Secretary deems necessary to provide such assurance. For a device that is purported or represented to be for a use in supporting or sustaining human life, the Secretary shall examine and identify the special controls, if any, that are necessary to provide adequate assurance of safety and effectiveness and describe how such controls provide such assurance.

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

(i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and

[*See main edition for text of* (ii)]

is to be subject, in accordance with section 360e of this title, to premarket approval to provide reasonable assurance of its safety and effectiveness.

If there is not sufficient information to establish a performance standard for a device to provide reasonable assurance of its safety and effectiveness, the Secretary may conduct such activities as may be necessary to develop or obtain such information.

[*See main edition for text of* (2) *and* (3); (*b*) *to* (*d*)]

(e) Classification changes

(1) Based on new information respecting a device, the Secretary may, upon his own initiative or upon petition of an interested person, by regulation (A) change such device's classification, and (B) revoke, because of the change in classification, any regulation or requirement in effect under section 360d or 360e of this title with respect to such device. In the promulgation of such a regulation respecting a device's classification, the Secretary may secure from the panel to which the device was last referred pursuant to subsection (c) of this section a recommendation respecting the proposed change in the device's classification and shall publish in the Federal Register any recommendation submitted to the Secretary by the panel respecting such change. A regulation under this subsection changing the classification of a device from class III to class II may provide that such classification shall not take effect until the effective date of a performance standard established under section 360d of this title for such device.

(2) By regulation promulgated under paragraph (1), the Secretary may change the classification of a device from class III—

(A) to class II if the Secretary determines that special controls would provide reasonable assurance of the safety and effectiveness of the device and that general controls would not provide reasonable assurance of the safety and effectiveness of the device, or

(B) to class I if the Secretary determines that general controls would provide reasonable assurance of the safety and effectiveness of the device.

(f) Initial classification and reclassification of certain devices

[*See main edition for text of* (1)]

(2)(A) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition.

(B)(i) Upon determining that a petition does not contain any deficiency which prevents the Secretary from making a decision on the petition, the Secretary may for good cause shown refer the petition to an appropriate panel established or authorized to be used under subsection (b) of this section. A panel to which such a petition has been referred shall not later than ninety days after the referral of the petition make a recommendation to the Secretary respecting approval or denial of the petition. Any such recommendation shall contain (I) a summary of the reasons for the recommendation, (II) a summary of the data upon which the recommendation is based, and (III) an identification of the risks to health (if any) presented by the device with respect to which the petition was filed. In the case of a petition for a device which is intended to be implanted in the human body or which is purported or represented to be for a use in supporting or sustaining human life, the panel shall recommend that the petition be denied unless the panel determines that the classification in class III of the device is not necessary to provide reasonable assurance of its safety and effectiveness. If the panel recommends that such petition be approved, it shall in its recommendation to the Secretary set forth its reasons for such recommendation.

[*See main edition for text of* (ii), (*C*)]

(3) If a manufacturer reports to the Secretary under section 360(k) of this title that a device is substantially equivalent to another device—

(i) which the Secretary has classified as a class III device under subsection (b) of this section,

(ii) which was introduced or delivered for introduction into interstate commerce for commercial distribution before December 1, 1990, and

(iii) for which no final regulation requiring premarket approval has been promulgated under section 360e(b) of this title,

the manufacturer shall certify to the Secretary that the manufacturer has conducted a reasonable search of all information known or otherwise available to the manufacturer respecting such other device and has included in the report under section 360(k) of this title a summary of and a citation to all adverse safety and effectiveness data respecting such other device and respecting the device for which the 360(k) report is being made and which has not been submitted to the Secretary under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety and effectiveness data described in the report.

[*See main edition for text of (g) and (h)*]

(i) Substantial equivalence

(1)(A) For purposes of determinations of substantial equivalence under subsection (f) of this section and section 360j(*l*) of this title, the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device—

(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including clinical data if deemed necessary by the Secretary, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and efficacy than the predicate device.

(B) For purposes of subparagraph (A), the term "different technological characteristics" means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

(2) A device may not be found to be substantially equivalent to a predicate device that has been removed from the market at the initiative of the Secretary or that has been determined to be misbranded or adulterated by a judicial order.

(3)(A) As part of a submission under section 360(k) of this title respecting a device, the person required to file a premarket notification under such section shall provide an adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request by any person.

(B) Any summary under subparagraph (A) respecting a device shall contain detailed information regarding data concerning adverse health effects and shall be made available to the public by the Secretary within 30 days of the issuance of a determination that such device is substantially equivalent to another device.

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 4(a), 5(a)-(c)(1), (3), 12(a), 18(a), 104 Stat. 4515, 4517, 4518, 4523, 4528.)

AMENDMENTS

1990—Subsec. (a)(1)(A)(ii). Pub. L. 101-629, § 5(a)(1), substituted "or to establish special controls" for "or to establish a performance standard".

Subsec. (a)(1)(B). Pub. L. 101-629, § 5(a)(2), amended subpar. (B) generally. Prior to amendment, subpar. (B) read as follows: "CLASS II, PERFORMANCE STANDARDS.—A device which cannot be classified as a class I device because the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, for which there is sufficient information to establish a performance standard to provide such assurance, and for which it is therefore necessary to establish for the device a performance standard under section 360d of this title to provide reasonable assurance of its safety and effectiveness."

Subsec. (a)(1)(C)(i). Pub. L. 101-629, § 5(a)(3), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: "it (I) cannot be classified as a class I device because insufficient information exists to determine that the controls authorized by or under sections 351, 352, 360, 360f, 360h, 360i, and 360j of this title are sufficient to provide reasonable assurance of the safety and effectiveness of the device and (II) cannot be classified as a class II device because insufficient information exists for the establishment of a performance standard to provide reasonable assurance of its safety and effectiveness, and".

Subsec. (e). Pub. L. 101-629, § 5(b), designated existing provisions as par. (1), redesignated cls. (1) and (2) as (A) and (B), respectively, and added par. (2).

Subsec. (f). Pub. L. 101-629, § 5(c)(3), inserted "and reclassification" before "of" in heading.

Subsec. (f)(2)(A). Pub. L. 101-629, § 5(c)(1), substituted "The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer" for "The manufacturer".

Subsec. (f)(2)(B)(i). Pub. L. 101-629, § 18(a), substituted "the Secretary may for good cause shown" for "the Secretary shall".

Subsec. (f)(3). Pub. L. 101-629, § 4(a), added par. (3).

Subsec. (i). Pub. L. 101-629, § 12(a), added subsec. (i).

REGULATIONS

Section 12(b) of Pub. L. 101-629 provided that: "Within 12 months of the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall issue regulations establishing the requirements of the summaries under section 513(i)(3) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360c(i)(3)], as added by the amendment made by subsection (a)."

DAILY WEAR SOFT OR DAILY WEAR NONHYDROPHILIC PLASTIC CONTACT LENSES

Section 4(b)(3) of Pub. L. 101-629 provided that:

"(A) Notwithstanding section 520(*l*)(5) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(*l*)(5)],

the Secretary of Health and Human Services shall not retain any daily wear soft or daily wear nonhydrophilic plastic contact lens in class III under such Act [this chapter] unless the Secretary finds that it meets the criteria set forth in section 513(a)(1)(C) of such Act [21 U.S.C. 360c(a)(1)(C)]. The finding and the grounds for the finding shall be published in the Federal Register. For any such lens, the Secretary shall make the determination respecting reclassification required in section 520(*l*)(5)(B) of such Act within 24 months of the date of the enactment of this paragraph [Nov. 28, 1990].

"(B) The Secretary of Health and Human Services may by notice published in the Federal Register extend the two-year period prescribed by subparagraph (A) for a lens for an additional period not to exceed one year.

"(C)(i) Before classifying a lens in class II pursuant to subparagraph (A), the Secretary of Health and Human Services shall pursuant to section 513(a)(1)(B) of such Act assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

"(ii) Prior to classifying a lens in class I pursuant to subparagraph (A), the Secretary shall assure that appropriate regulatory safeguards are in effect which provide reasonable assurance of the safety and effectiveness of such lens, including clinical and preclinical data if deemed necessary by the Secretary.

"(D) Notwithstanding section 520(*l*)(5) of such Act, if the Secretary of Health and Human Services has not made the finding and published the finding required by subparagraph (A) within 36 months of the date of the enactment of this subparagraph [Nov. 28, 1990], the Secretary shall issue an order placing the lens in class II.

"(E) Any person adversely affected by a final regulation under this paragraph revising the classification of a lens may challenge the revision of the classification of such lens only by filing a petition under section 513(e) for a classification change."

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 360, 360d, 360e, 360g, 360j of this title.

§ 360d. Performance standards

(a) Reasonable assurance of safe and effective performance; periodic evaluation

(1) The special controls required by section 360c(a)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device. A class III device may also be considered a class II device for purposes of establishing a standard for the device under this section if the device has been reclassified as a class II device under a regulation under section 360c(e) of this title but such regulation provides that the reclassification is not to take effect until the effective date of such a standard for the device.

[*See main edition for text of (2) to (4)*]

(b) Establishment of a standard

(1)(A) The Secretary shall publish in the Federal Register a notice of proposed rulemaking for the establishment, amendment, or revocation of any performance standard for a device.

(B) A notice of proposed rulemaking for the establishment or amendment of a performance standard for a device shall—

(i) set forth a finding with supporting justification that the performance standard is appropriate and necessary to provide reasonable assurance of the safety and effectiveness of the device,

(ii) set forth proposed findings with respect to the risk of illness or injury that the performance standard is intended to reduce or eliminate,

(iii) invite interested persons to submit to the Secretary, within 30 days of the publication of the notice, requests for changes in the classification of the device pursuant to section 360c(e) of this title based on new information relevant to the classification, and

(iv) invite interested persons to submit an existing performance standard for the device, including a draft or proposed performance standard, for consideration by the Secretary.

(C) A notice of proposed rulemaking for the revocation of a performance standard shall set forth a finding with supporting justification that the performance standard is no longer necessary to provide reasonable assurance of the safety and effectiveness of a device.

(D) The Secretary shall provide for a comment period of not less than 60 days.

(2) If, after publication of a notice in accordance with paragraph (1), the Secretary receives a request for a change in the classification of the device, the Secretary shall, within 60 days of the publication of the notice, after consultation with the appropriate panel under section 360c of this title, either deny the request or give notice of an intent to initiate such change under section 360c(e) of this title.

(3)(A) After the expiration of the period for comment on a notice of proposed rulemaking published under paragraph (1) respecting a performance standard and after consideration of such comments and any report from an advisory committee under paragraph (5), the Secretary shall (i) promulgate a regulation establishing a performance standard and publish in the Federal Register findings on the matters referred to in paragraph (1), or (ii) publish a notice terminating the proceeding for the development of the standard together with the reasons for such termination. If a notice of termination is published, the Secretary shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

(B) A regulation establishing a performance standard shall set forth the date or dates upon which the standard shall take effect, but no such regulation may take effect before one year after the date of its publication unless (i) the Secretary determines that an earlier effective

date is necessary for the protection of the public health and safety, or (ii) such standard has been established for a device which, effective upon the effective date of the standard, has been reclassified from class III to class II. Such date or dates shall be established so as to minimize, consistent with the public health and safety, economic loss to, and disruption or dislocation of, domestic and international trade.

(4)(A) The Secretary, upon his own initiative or upon petition of an interested person may by regulation, promulgated in accordance with the requirements of paragraphs (1), (2), and (3)(B) of this subsection, amend or revoke a performance standard.

(B) The Secretary may declare a proposed amendment of a performance standard to be effective on and after its publication in the Federal Register and until the effective date of any final action taken on such amendment if he determines that making it so effective is in the public interest. A proposed amendment of a performance standard made so effective under the preceding sentence may not prohibit, during the period in which it is so effective, the introduction or delivery for introduction into interstate commerce of a device which conforms to such standard without the change or changes provided by such proposed amendment.

(5)(A) The Secretary—

(i) may on his own initiative refer a proposed regulation for the establishment, amendment, or revocation of a performance standard, or

(ii) shall, upon the request of an interested person which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation,

to an advisory committee of experts, established pursuant to subparagraph (B), for a report and recommendation with respect to any matter involved in the proposed regulation which requires the exercise of scientific judgment. If a proposed regulation is referred under this subparagraph to an advisory committee, the Secretary shall provide the advisory committee with the data and information on which such proposed regulation is based. The advisory committee shall, within sixty days of the referral of a proposed regulation and after independent study of the data and information furnished to it by the Secretary and other data and information before it, submit to the Secretary a report and recommendation respecting such regulation, together with all underlying data and information and a statement of the reason or basis for the recommendation. A copy of such report and recommendation shall be made public by the Secretary.

(B) The Secretary shall establish advisory committees (which may not be panels under section 360c of this title) to receive referrals under subparagraph (A). The Secretary shall appoint as members of any such advisory committee persons qualified in the subject matter to be referred to the committee and of appropriately diversified professional background, except that the Secretary may not appoint to such a committee any individual who is in the regular full-time employ of the United States and engaged in the administration of this chapter. Each such committee shall include as nonvoting members a representative of consumer interests and a representative of interests of the device manufacturing industry. Members of an advisory committee who are not officers or employees of the United States, while attending conferences or meetings of their committee or otherwise serving at the request of the Secretary, shall be entitled to receive compensation at rates to be fixed by the Secretary, which rates may not exceed the daily equivalent of the rate in effect for grade GS-18 of the General Schedule, for each day (including traveltime) they are so engaged; and while so serving away from their homes or regular places of business each member may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5 for persons in the Government service employed intermittently. The Secretary shall designate one of the members of each advisory committee to serve as chairman thereof. The Secretary shall furnish each advisory committee with clerical and other assistance, and shall by regulation prescribe the procedures to be followed by each such committee in acting on referrals made under subparagraph (A).

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 6(a), (b)(1), 18(b), 104 Stat. 4519, 4528.)

AMENDMENTS

1990—Subsec. (a)(1). Pub. L. 101-629, § 6(a)(1), substituted "The special controls required by section 360c(a)(1)(B) of this title shall include performance standards for a class II device if the Secretary determines that a performance standard is necessary to provide reasonable assurance of the safety and effectiveness of the device." for "The Secretary may by regulation, promulgated in accordance with this section, establish a performance standard for a class II device."

Subsec. (b). Pub. L. 101-629, § 6(a)(2), (3), redesignated subsec. (g) as (b) and struck out former subsec. (b) which read as follows:

"(1) A proceeding for the development of a performance standard for a device shall be initiated by the Secretary by the publication in the Federal Register of notice of the opportunity to submit to the Secretary a request (within fifteen days of the date of the publication of the notice) for a change in the classification of the device based on new information relevant to its classification.

"(2) If, after publication of a notice pursuant to paragraph (1) the Secretary receives a request for a change in the device's classification, he shall, within sixty days of the publication of such notice and after consultation with the appropriate panel under section 360c of this title, by order published in the Federal Register, either deny the request for change in classification or give notice of his intent to initiate such a change under section 360c(e) of this title."

Subsec. (b)(1), (2). Pub. L. 101-629, § 6(a)(4), amended pars. (1) and (2) generally. Prior to amendment, pars. (1) and (2) read as follows:

"(1)(A) After publication pursuant to subsection (c) of this section of a notice respecting a performance standard for a device, the Secretary shall either—

"(i) publish, in the Federal Register in a notice of proposed rulemaking, a proposed performance standard for the device (I) developed by an offeror under such notice and accepted by the Secretary,

(II) developed under subsection (c)(4) of this section, (III) accepted by the Secretary under subsection (d) of this section, or (IV) developed by him under subsection (f) of this section, or

"(ii) issue a notice in the Federal Register that the proceeding is terminated together with the reasons for such termination.

"(B) If the Secretary issues under subparagraph (A)(ii) a notice of termination of a proceeding to establish a performance standard for a device, he shall (unless such notice is issued because the device is a banned device under section 360f of this title) initiate a proceeding under section 360c(e) of this title to reclassify the device subject to the proceeding terminated by such notice.

"(2) A notice of proposed rulemaking for the establishment of a performance standard for a device published under paragraph (1)(A)(i) shall set forth proposed findings with respect to the degree of the risk of illness or injury designed to be eliminated or reduced by the proposed standard and the benefit to the public from the device."

Subsec. (b)(3)(A)(i). Pub. L. 101-629, § 6(b)(1)(A), substituted "paragraph (1)" for "paragraph (2)".

Subsec. (b)(4)(A). Pub. L. 101-629, § 6(b)(1)(B), substituted "paragraphs (1), (2), and (3)(B)" for "paragraphs (2) and (3)(B)".

Subsec. (b)(4)(B). Pub. L. 101-629, § 18(b)(1), which directed the amendment of par. (3)(B) by striking out ", after affording all interested persons an opportunity for an informal hearing," was executed by striking out that language after "if he determines" in par. (4)(B), to reflect the probable intent of Congress.

Subsec. (b)(5)(A)(ii). Pub. L. 101-629, § 18(h)(2), which directed the amendment of par. (4)(A)(ii) by substituting "which demonstrates good cause for referral and which is made before the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation," for "unless" and all that follows in cl. (ii), was executed by substituting the new language for "unless the Secretary finds the request to be without good cause or the request is made after the expiration of the period for submission of comments on such proposed regulation refer such proposed regulation," in par. (5)(A)(ii), to reflect the probable intent of Congress.

Subsecs. (c) to (f). Pub. L. 101-629, § 6(a)(2), struck out subsec. (c) relating to invitations for standards, subsec. (d) relating to acceptance of certain existing standards, subsec. (e) relating to acceptance of offers to develop standards, and subsec. (f) relating to development of standards by the Secretary after publication of notice inviting submissions or offers of standards.

Subsec. (g). Pub. L. 101-629, § 6(a)(3), redesignated subsec. (g) as (b).

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

§ 360e. Premarket approval

[*See main edition for text of (a) and (b)*]

(c) Application for premarket approval

[*See main edition for text of (1)*]

(2) Upon receipt of an application meeting the requirements set forth in paragraph (1), the Secretary—

(A) may on the Secretary's own initiative refer such application, or

(B) shall, upon the request of an applicant unless the Secretary finds that the information in the application which would be reviewed by a panel substantially duplicates information which has previously been reviewed by a panel appointed under section 360c of this title,

refer such application to the appropriate panel under section 360c of this title for study and for submission (within such period as he may establish) of a report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation.

[*See main edition for text of (d)*]

(e) Withdrawal and temporary suspension of approval of application

[*See main edition for text of (1) and (2)*]

(3) If, after providing an opportunity for an informal hearing, the Secretary determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death, the Secretary shall by order temporarily suspend the approval of the application approved under this section. If the Secretary issues such an order, the Secretary shall proceed expeditiously under paragraph (1) to withdraw such application.

[*See main edition for text of (f) to (h)*]

(i) Revision

(1) Before December 1, 1995, the Secretary shall by order require manufacturers of devices, which were introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, and which are subject to revision of classification under paragraph (2), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturer respecting such devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require the manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(2) After the issuance of an order under paragraph (1) but before December 1, 1995, the Secretary shall publish a regulation in the Federal Register for each device—

(A) which the Secretary has classified as a class III device, and

(B) for which no final regulation has been promulgated under subsection (b) of this section,

revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title. Before the publication of a

regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this paragraph and provide reasonable opportunity for the submission of comments on any such regulation. No regulation requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of its publication in the Federal Register as a proposed regulation.

(3) The Secretary shall, as promptly as is reasonably achievable, but not later than 12 months after the effective date of the regulation requiring a device to remain in class III, establish a schedule for the promulgation of a subsection (b) of this section regulation for each device which is subject to the regulation requiring the device to remain in class III.

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 4(b)(1), 9(a), 18(c), 104 Stat. 4515, 4521, 4528.)

AMENDMENTS

1990—Subsec. (c)(2). Pub. L. 101-629, § 18(c), substituted "the Secretary—" for "the Secretary shall" and added subpars. (A) and (B).

Subsec. (e). Pub. L. 101-629, § 9(a)(2), inserted "and temporary suspension" after "Withdrawal" in heading.

Subsec. (e)(3). Pub. L. 101-629, § 9(a)(1), added par. (3).

Subsec. (i). Pub. L. 101-629, § 4(b)(1), added subsec. (i).

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 351, 353, 360, 360c, 360g, 360j, 381 of this title; title 35 section 156.

§ 360f. Banned devices

(a) General rule

Whenever the Secretary finds, on the basis of all available data and information, that—

[*See main edition for text of (1) and (2)*]

he may initiate a proceeding to promulgate a regulation to make such device a banned device.

[*Sec main edition for text of (b)*]

(As amended Nov. 28, 1990, Pub. L. 101-629, § 18(d), 104 Stat. 4529.)

AMENDMENTS

1990—Subsec. (a). Pub. L. 101-629 struck out "and after consultation with the appropriate panel or panels under section 360c of this title" after "data and information" in introductory provisions and struck out at end "The Secretary shall afford all interested persons opportunity for an informal hearing on a regulation proposed under this subsection."

§ 360g. Judicial review

(a) Petition; record

Not later than thirty days after—

[*See main edition for text of (1) to (5)*]

(6) the issuance of an order under section 360j(f)(2) of this title,

[*See main edition for text of (7)*]

(8) an order pursuant to section 360c(i) of this title,

(9) a regulation under section 360e(i)(2) or 360j(l)(5)(B) of this title, or

(10) an order under section 360j(c)(4)(B) of this title,

any person adversely affected by such regulation or order may file a petition with the United States Court of Appeals for the District of Columbia or for the circuit wherein such person resides or has his principal place of business for judicial review of such regulation or order. A copy of the petition shall be transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary shall file in the court the record of the proceedings on which the Secretary based his regulation or order as provided in section 2112 of title 28. For purposes of this section, the term "record" means all notices and other matter published in the Federal Register with respect to the regulation or order reviewed, all information submitted to the Secretary with respect to such regulation or order, proceedings of any panel or advisory committee with respect to such regulation or order, any hearing held with respect to such regulation or order, and any other information identified by the Secretary, in the administrative proceeding held with respect to such regulation or order, as being relevant to such regulation or order.

[*See main edition for text of (b) to (f)*]

(As amended Nov. 28, 1990, Pub. L. 101-629, § 13, 104 Stat. 4524.)

AMENDMENTS

1990—Subsec. (a)(8) to (10). Pub. L. 101-629 added pars. (8) to (10).

§ 360h. Notification and other remedies

[*See main edition for text of (a) to (d)*]

(e) Recall authority

(1) If the Secretary finds that there is a reasonable probability that a device intended for human use would cause serious, adverse health consequences or death, the Secretary shall issue an order requiring the appropriate person (including the manufacturers, importers, distributors, or retailers of the device)—

(A) to immediately cease distribution of such device, and

(B) to immediately notify health professionals and device user facilities of the order and to instruct such professionals and facilities to cease use of such device.

The order shall provide the person subject to the order with an opportunity for an informal hearing, to be held not later than 10 days after the date of the issuance of the order, on the actions required by the order and on whether the order should be amended to require a recall of such device. If, after providing an opportunity for such a hearing, the Secretary determines that inadequate grounds exist to support the actions required by the order, the Secretary shall vacate the order.

(2)(A) If, after providing an opportunity for an informal hearing under paragraph (1), the Secretary determines that the order should be amended to include a recall of the device with respect to which the order was issued, the Secretary shall, except as provided in subparagraphs (B) and (C), amend the order to require a recall. The Secretary shall specify a timetable in which the device recall will occur and shall require periodic reports to the Secretary describing the progress of the recall.

(B) An amended order under subparagraph (A)—

(i) shall—

(I) not include recall of a device from individuals, and

(II) not include recall of a device from device user facilities if the Secretary determines that the risk of recalling such device from the facilities presents a greater health risk than the health risk of not recalling the device from use, and

(ii) shall provide for notice to individuals subject to the risks associated with the use of such device.

In providing the notice required by clause (ii), the Secretary may use the assistance of health professionals who prescribed or used such a device for individuals. If a significant number of such individuals cannot be identified, the Secretary shall notify such individuals pursuant to section 375(b) of this title.

(3) The remedy provided by this subsection shall be in addition to remedies provided by subsections (a), (b), and (c) of this section.

(As amended Nov. 28, 1990, Pub. L. 101-629, § 8, 104 Stat. 4520.)

AMENDMENTS

1990—Subsec. (e). Pub. L. 101-629 added subsec. (e).

§ 360i. Records and reports on devices

(a) General rule

Every person who is a manufacturer, importer, or distributor of a device intended for human use shall establish and maintain such records, make such reports, and provide such information, as the Secretary may by regulation reasonably require to assure that such device is not adulterated or misbranded and to otherwise assure its safety and effectiveness. Regulations prescribed under the preceding sentence—

[*See main edition for text of (1) to (3)*]

(4) may not require that the identity of any patient be disclosed in records, reports, or information required under this subsection unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under this chapter;

(5) may not require a manufacturer, importer, or distributor of a class I device to—

[*See main edition for text of (A)*]

(B) to submit for such a device to the Secretary any report or information—

[*See main edition for text of (i) and (ii)*]

unless such report or information is necessary to determine if the device should be reclassified or if the device is adulterated or misbranded; and

(6) shall require distributors who submit such reports to submit copies of the reports to the manufacturer of the device for which the report was made.

In prescribing such regulations, the Secretary shall have due regard for the professional ethics of the medical profession and the interests of patients. The prohibitions of paragraph (4) of this subsection continue to apply to records, reports, and information concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(b) User reports

(1)(A) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that there is a probability that a device has caused or contributed to the death of a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the Secretary and, if the identity of the manufacturer is known, to the manufacturer of the device. In the case of deaths, the Secretary may by regulation prescribe a shorter period for the reporting of such information.

(B) Whenever a device user facility receives or otherwise becomes aware of information that reasonably suggests that there is a probability that a device has caused or contributed to the serious illness of, or serious injury to, a patient of the facility, the facility shall, as soon as practicable but not later than 10 working days after becoming aware of the information, report the information to the manufacturer of the device or to the Secretary if the identity of the manufacturer is not known.

(C) Each device user facility shall submit to the Secretary on a semi-annual basis a summary of the reports made under subparagraphs (A) and (B). Such summary shall be submitted on January 1 and July 1 of each year. The summary shall be in such form and contain such information from such reports as the Secretary may require and shall include—

(i) sufficient information to identify the facility which made the reports for which the summary is submitted,

(ii) in the case of any product which was the subject of a report, the product name, serial number, and model number,

(iii) the name and the address of the manufacturer of such device, and

(iv) a brief description of the event reported to the manufacturer.

The Secretary may by regulation alter the frequency and timing of reports required by this subparagraph.

(D) For purposes of subparagraphs (A), (B), and (C), a device user facility shall be treated as having received or otherwise become aware of information with respect to a device of that facility when medical personnel who are employed by or otherwise formally affiliated with the facility receive or otherwise become aware of information with respect to that device in the course of their duties.

(2) The Secretary may not disclose the identity of a device user facility which makes a report under paragraph (1) except in connection with—

(A) an action brought to enforce section 331(q) of this title,

(B) a communication to a manufacturer of a device which is the subject of a report under paragraph (1), or

(C) a disclosure required under subsection (a) of this section.

This paragraph does not prohibit the Secretary from disclosing the identity of a device user facility making a report under paragraph (1) or any information in such a report to employees of the Department of Health and Human Services, to the Department of Justice, or to the duly authorized committees and subcommittees of the Congress.

(3) No report made under paragraph (1) by—

(A) a device user facility,

(B) an individual who is employed by or otherwise formally affiliated with such a facility, or

(C) a physician who is not required to make such a report,

shall be admissible into evidence or otherwise used in any civil action involving private parties unless the facility, individual, or physician who made the report had knowledge of the falsity of the information contained in the report.

(4) A report made under paragraph (1) does not affect any obligation of a manufacturer who receives the report to file a report as required under subsection (a) of this section.

(5) For purposes of this subsection:

(A) The term "device user facility" means a hospital, ambulatory surgical facility, nursing home, or outpatient treatment facility which is not a physician's office. The Secretary may by regulation include an outpatient diagnostic facility which is not a physician's office in such term.

(B) The terms "serious illness" and "serious injury" mean illness or injury, respectively, that—

(i) is life threatening,

(ii) results in permanent impairment of a body function or permanent damage to a body structure, or

(iii) necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(c) Persons exempt

Subsection (a) of this section shall not apply to—

(1) any practitioner who is licensed by law to prescribe or administer devices intended for use in humans and who manufactures or imports devices solely for use in the course of his professional practice;

(2) any person who manufactures or imports devices intended for use in humans solely for such person's use in research or teaching and not for sale (including any person who uses a device under an exemption granted under section 360j(g) of this title); and

(3) any other class of persons as the Secretary may by regulation exempt from subsection (a) of this section upon a finding that compliance with the requirements of such subsection by such class with respect to a device is not necessary to (A) assure that a device is not adulterated or misbranded or (B) otherwise to assure its safety and effectiveness.

(d) Certification

Each manufacturer, importer, and distributor required to make reports under subsection (a) of this section shall submit to the Secretary annually a statement certifying that—

(1) the manufacturer, importer, or distributor did file a certain number of such reports, or

(2) the manufacturer, importer, or distributor did not file any report under subsection (a) of this section.

(e) Device tracking

Every person who registers under section 360 of this title and is engaged in the manufacture of—

(1) a device the failure of which would be reasonably likely to have serious adverse health consequences and which is (A) a permanently implantable device, or (B) a life sustaining or life supporting device used outside a device user facility, or

(2) any other device which the Secretary may designate,

shall adopt a method of device tracking.

(f) Report of removals and corrections

(1) Except as provided in paragraph (2), the Secretary shall by regulation require a manufacturer, importer, or distributor of a device to report promptly to the Secretary any correction or removal of a device undertaken by such manufacturer, importer, or distributor if the removal or correction was undertaken—

(A) to reduce a risk to health posed by the device, or

(B) to remedy a violation of this chapter caused by the device which may present a risk to health.

A manufacturer, importer, or distributor of a device who undertakes a correction or removal of a device which is not required to be reported under this paragraph shall keep a record of such correction or removal.

(2) No report of the corrective action or removal of a device may be required under paragraph (1) if a report of the corrective action or removal is required and has been submitted under subsection (a) of this section.

(3) For purposes of paragraphs (1) and (2), the terms "correction" and "removal" do not include routine servicing.

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 2(a), 3(a)(1), (b)(1), 7, 104 Stat. 4511, 4513, 4514, 4520.)

AMENDMENTS

1990—Subsec. (a)(6). Pub. L. 101-629, § 3(a)(1), added par. (6).

Subsecs. (b), (c). Pub. L. 101-629, § 2(a), added subsec. (b) and redesignated former subsec. (b) as (c).

Subsecs. (d), (e). Pub. L. 101-629, § 3(b)(1), added subsecs. (d) and (e).

Subsec. (f). Pub. L. 101-629, § 7, added subsec. (f).

EFFECTIVE DATE OF 1990 AMENDMENT

Section 2(c) of Pub. L. 101-629 provided that: "Section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)], as added by the amendment made by subsection (a), shall take effect—

"(1) upon the effective date of regulations promulgated under subsection (b) [set out below], or

"(2) upon the expiration of 12 months from the date of the enactment of this Act [Nov. 28, 1990], whichever occurs first."

Section 3(a)(2) of Pub. L. 101-629 provided that: "Section 519(a)(6) [21 U.S.C. 360i(a)(6)], as added by the amendment made by paragraph (1), shall take effect upon the effective date of final regulations under subsection (c) [set out below]."

Section 3(b)(3) of Pub. L. 101-629 provided that: "Section 519(e) [21 U.S.C. 360i(e)], as added by the amendment made by paragraph (1), shall take effect upon the effective date of final regulations under subsection (c) [set out below]."

REGULATIONS

Section 2(b) of Pub. L. 101-629 provided that: "The Secretary of Health and Human Services shall promulgate regulations to implement section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)], as added by the amendment made by subsection (a) (including a definition of the summary required by paragraph (1)(C) of such section) not later than 12 months after the date of enactment of this Act [Nov. 28, 1990]. In promulgating the regulations, the Secretary shall minimize the administrative burdens on device user facilities consistent with the need to assure adequate information."

Section 3(c) of Pub. L. 101-629 provided that:

"(1)(A) Not later than 9 months after the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall issue proposed regulations—

"(i) to require distributors of devices to establish and maintain records and to make reports (including reports required by part 803 of title 21 of the Code of Federal Regulations) under section 519(a)(6) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(a)(6)], and

"(ii) to implement section 519(e) of such Act.

The Secretary may exempt from regulations described in clause (i) classes of distributors of class I and class II devices from whom reports are not necessary for the protection of the public health.

"(B) Regulations under subparagraph (A) shall—

"(i) require appropriate methods for maintenance of records to ensure that patients who receive devices can be provided the notification required by such Act [this chapter],

"(ii) require that manufacturers adopt effective methods of tracking devices,

"(iii) take into account the position of distributors in the device distribution process, and

"(iv) include such other requirements as the Secretary deems necessary for the adoption of an effective user tracking program under section 519(e) of such Act.

"(2) Not later than 18 months after the date of the enactment of this Act, the Secretary shall issue final regulations to implement sections 519(a)(6) and 519(e) of the Federal Food, Drug, and Cosmetic Act. If the Secretary does not promulgate such final regulations upon the expiration of such 18 months, the Congress finds that there is good cause for the proposed regulations to be considered as the final regulations without response to comment because the implementation of sections 519(a)(6) and 519(e) of such Act are essential to protect the health of patients who use such devices. Consequently, in such event, the proposed regulations issued under paragraph (1) shall become final regulations as of the expiration of such 18 months. There shall be promptly published in the Federal Register notice of the new status of the proposed regulations."

INFORMATION CONCERNING REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Section 2(d) of Pub. L. 101-629 provided that: "During the 18-month period beginning on the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall inform device user facilities (as defined in section 519(b)(5)(A) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)(5)(A)]) and manufacturers and distributors of devices respecting the requirements of section 519(b) of such Act. Additionally, the Secretary, to the extent practicable, shall provide persons subject to the requirements of such section assistance in the form of publications regarding such requirements."

STUDY OF REPORTING REQUIREMENTS; COMPLIANCE BY DEVICE USER FACILITIES; ACTIONS BY MANUFACTURERS; COST EFFECTIVENESS; RECOMMENDATIONS

Section 2(e) of Pub. L. 101-629 provided that: "Not more than 36 months after the date of the enactment of this Act [Nov. 28, 1990], the Comptroller General of the United States shall conduct a study of—

"(1) the compliance by device user facilities (as defined in section 519(b)(5)(A) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)(5)(A)]) with the requirements of section 519(b) of such Act,

"(2) the actions taken by the manufacturers of devices in response to reports made to them under such section,

"(3) the cost effectiveness of such requirements and their implementation, and

"(4) any recommendations for improvements to such requirements.

The Comptroller General shall complete the study and submit a report on the study not later than 45 months from the date of the enactment of this Act. The report shall be submitted to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate and to the Secretary of Health and Human Services."

REPORT TO CONGRESS ON REPORTING REQUIREMENTS FOR DEVICE USER FACILITIES

Section 2(f) of Pub. L. 101-629 provided that: "Not later than 36 months after the date of enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report that contains an evaluation of the requirements of section 519(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360i(b)]. In preparing the report, the Secretary shall consult with individuals and organizations with an interest in health care and consumer issues. At a minimum, the report shall contain—

"(1) an evaluation of the safety benefits of the requirements,

"(2) an evaluation of the burdens placed on the Food and Drug Administration and on device user facilities by the requirements,

"(3) an evaluation of the cost-effectiveness of the requirements, and

"(4) recommendations for legislative reform."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 352, 360c, 360e, 360g, 360j, 374 of this title.

§ 360j. General provisions respecting control of devices intended for human use

[*See main edition for text of (a) and (b)*]

(c) Trade secrets

Any information reported to or otherwise obtained by the Secretary or his representative under section 360c, 360d, 360e, 360f, 360h, 360i, or 374 of this title or under subsection (f) or (g) of this section which is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of such section shall be considered confidential and shall not be disclosed and may not be used by the Secretary as the basis for the reclassification of a device from class III to class II or class I or as the basis for the establishment or amendment of a performance standard under section 360d of this title for a device reclassified from class III to class II, except (1) in accordance with subsection (h) of this section, and (2) that such information may be disclosed to other officers or employees concerned with carrying out this chapter or when relevant in any proceeding under this chapter (other than section 360c or 360d of this title).

[*See main edition for text of (d) and (e)*]

(f) Good manufacturing practice requirements

(1)(A) The Secretary may, in accordance with subparagraph (B), prescribe regulations requiring that the methods used in, and the facilities and controls used for, the manufacture, preproduction design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device), packing, storage, and installation of a device conform to current good manufacturing practice, as prescribed in such regulations, to assure that the deviee will be safe and effective and otherwise in compliance with this chapter.

[*See main edition for text of (B)*]

The Secretary shall provide the advisory committee a reasonable time to make its recommendation with respect to proposed regulations under subparagraph (A).

[*See main edition for text of (2) and (3); (g)*]

(h) Release of information respecting safety and effectiveness

[*See main edition for text of (1) and (2)*]

(3) Except as provided in paragraph (4), any information respecting a device which is made available pursuant to paragraph (1) or (2) of this subsection (A) may not be used to establish the safety or effectiveness of another device for purposes of this chapter by any person other than the person who submitted the information so made available, and (B) shall be made available subject to subsection (c) of this section.

(4)(A) Any information contained in an application for premarket approval filed with the Secretary pursuant to section 360e(c) of this title, including clinical and preclinical tests or studies, but excluding descriptions of methods of manufacture and product composition, that demonstrates the safety and effectiveness of a device shall be available 1 year after the original application for the fourth device of a kind has been approved by the Secretary, for use by the Secretary in approving devices, or determining whether a product development protocol has been completed, under section 360e of this title, establishing a performance standard under section 360d of this title, and reclassifying devices under subsections (e) and (f) of section 360c of this title, and subsection (*l*)(2) of this section. The Secretary shall deem devices that incorporate the same technologies, have the same principles of operation, and are intended for the same use or uses to be within a kind of device.

(B) The Secretary, contemporaneously with the approval of the fourth device of a kind, shall publish an order in the Federal Register identifying the four devices of a kind that have been approved under section 360e of this title and the date on which the data contained in premarket approval applications for the devices will be available to the Secretary for use, as described in subparagraph (A).

(C) The publicly available detailed summaries of information respecting the safety and effectiveness of devices required by paragraph (1)(A) shall be available for use by the Secretary as the evidentiary basis for the regulatory action described in subparagraph (A).

(D)(i) This paragraph shall become effective—

(I) on November 15, 1990, for devices for which four devices of a kind were approved on or before December 31, 1987, and

(II) on November 15, 1991, for devices not described in subclause (I).

(ii) For each device described in clause (i)(I), the Secretary shall publish a notice in the Federal Register setting forth the date, which shall be not earlier than 1 year after the date of the notice, that data identified in subparagraph (A) shall be available for the use of the Secretary.

(E)(i) Except as provided in clause (ii), the approval date of a device, for purposes of this paragraph, shall be the date of the letter of the Secretary to the applicant approving a device under section 360e of this title and permitting the applicant to commercially distribute the device.

(ii) For each device described in subparagraph (D)(i)(II) for which the original application for a fourth device of a kind is approved by the Secretary before November 1, 1991, the approval date of the fourth device of a kind shall be deemed to be November 15, 1991.

(F) Any challenge to an order under subparagraph (B) shall be made not later than 30 days after the date of the Federal Register notice referred to in such subparagraph.

(i) Proceedings of advisory panels and committees

Each panel under section 360c of this title and each advisory committee established under section 360d(b)(5)(B) or 360e(g) of this title or under subsection (f) of this section shall make and maintain a transcript of any proceeding of the panel or committee. Each such panel and committee shall delete from any transcript made pursuant to this subsection information which under subsection (c) of this section is to be considered confidential.

(j) Traceability

Except as provided in section 360i(e) of this title, no regulation under this chapter may impose on a type or class of device requirements for the traceability of such type or class of device unless such requirements are necessary to assure the protection of the public health.

[*See main edition for text of (k)*]

(l) Transitional provisions for devices considered as new drugs or antibiotic drugs

[*See main edition for text of (1)*]

(2) The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer or importer of a device classified under paragraph (1) may petition the Secretary (in such form and manner as he shall prescribe) for the issuance of an order classifying the device in class I or class II. Within thirty days of the filing of such a petition, the Secretary shall notify the petitioner of any deficiencies in the petition which prevent the Secretary from making a decision on the petition. Except as provided in paragraph (3)(D)(ii), within one hundred and eighty days after the filing of a petition under this paragraph, the Secretary shall, after consultation with the appropriate panel under section 360c of this title, by order either deny the petition or order the classification, in accordance with the criteria prescribed by section 360c(a)(1)(A) of this title or 360c(a)(1)(B) of this title, of the device in class I or class II.

[*See main edition for text of (3) and (4)*]

(5)(A) Before December 1, 1991, the Secretary shall by order require manufacturers of devices described in paragraph (1), which are subject to revision of classification under subparagraph (B), to submit to the Secretary a summary of and citation to any information known or otherwise available to the manufacturers respecting the devices, including adverse safety or effectiveness information which has not been submitted under section 360i of this title. The Secretary may require a manufacturer to submit the adverse safety or effectiveness data for which a summary and citation were submitted, if such data are available to the manufacturer.

(B) Except as provided in subparagraph (C), after the issuance of an order under subparagraph (A) but before December 1, 1992, the Secretary shall publish a regulation in the Federal Register for each device which is classified in class III under paragraph (1) revising the classification of the device so that the device is classified into class I or class II, unless the regulation requires the device to remain in class III. In determining whether to revise the classification of a device or to require a device to remain in class III, the Secretary shall apply the criteria set forth in section 360c(a) of this title. Before the publication of a regulation requiring a device to remain in class III or revising its classification, the Secretary shall publish a proposed regulation respecting the classification of a device under this subparagraph and provide an opportunity for the submission of comments on any such regulation. No regulation under this subparagraph requiring a device to remain in class III or revising its classification may take effect before the expiration of 90 days from the date of the publication in the Federal Register of the proposed regulation.

(C) The Secretary may by notice published in the Federal Register extend the period prescribed by subparagraph (B) for a device for an additional period not to exceed 1 year.

(m) Humanitarian device exemption

(1) To the extent consistent with the protection of the public health and safety and with ethical standards, it is the purpose of this subsection to encourage the discovery and use of devices intended to benefit patients in the treatment and diagnosis of diseases or conditions that affect fewer than 4,000 individuals in the United States.

(2) The Secretary may grant a request for an exemption from the effectiveness requirements of sections 360d and 360e of this title for a device for which the Secretary finds that—

(A) the device is designed to treat or diagnose a disease or condition that affects fewer than 4,000 individuals in the United States,

(B) the device would not be available to a person with a disease or condition referred to in subparagraph (A) unless the Secretary grants such an exemption and there is no comparable device, other than under this exemption, available to treat or diagnose such disease or condition, and

(C) the device will not expose patients to an unreasonable or significant risk of illness or injury and the probable benefit to health from the use of the device outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment.

(3) No person granted an exemption under paragraph (2) with respect to a device may sell the device for an amount that exceeds the costs of research and development, fabrication, and distribution of the device.

(4) Devices granted an exemption under paragraph (2) may only be used—

(A) in facilities that have established, in accordance with regulations of the Secretary, a local institutional review committee to super-

vise clinical testing of devices in the facilities, and

(B) if, before the use of a device, an institutional review committee approves the use in the treatment or diagnosis of a disease or condition referred to in paragraph (2)(A).

(5) An exemption under paragraph (2) shall be for a term of 18 months and may only be initially granted in the 5-year period beginning on the date regulations under paragraph (6) take effect. The Secretary may extend such an exemption for a period of 18 months if the Secretary is able to make the findings set forth in paragraph (2) and if the applicant supplies information demonstrating compliance with paragraph (3). An exemption may be extended more than once and may be extended after the expiration of such 5-year period.

(6) Within one year of November 28, 1990, the Secretary shall issue regulations to implement this subsection.

(As amended Nov. 28, 1990, Pub. L. 101-629, §§ 3(b)(2), 4(b)(2), 5(c)(2), 6(b)(2), 11, 14(a), 18(e), (f), 104 Stat. 4514, 4516, 4518, 4519, 4522, 4524, 4529.)

AMENDMENTS

1990—Subsec. (c). Pub. L. 101-629, § 11(1), substituted "from class III to class II or class I" for "under section 360c of this title from class III to class II" and inserted "(1) in accordance with subsection (h) of this section, and (2)" after "except".

Subsec. (f)(1)(A). Pub. L. 101-629, § 18(e), inserted "pre-production design validation (including a process to assess the performance of a device but not including an evaluation of the safety or effectiveness of a device)," after "manufacture,".

Subsec. (h)(3). Pub. L. 101-629, § 11(2)(A), substituted "Except as provided in paragraph (4), any" for "Any".

Subsec. (h)(4). Pub. L. 101-629, § 11(2)(B), added par. (4).

Subsec. (i). Pub. L. 101-629, § 6(b)(2), substituted "section 360d(b)(5)(B)" for "section 360d(g)(5)(B)".

Subsec. (j). Pub. L. 101-629, § 3(b)(2), substituted "Except as provided in section 360l(e) of this title, no" for "No".

Subsec. (*l*)(2). Pub. L. 101-629, § 18(f), struck out "and after affording the petitioner an opportunity for an informal hearing" after "under this paragraph".

Pub. L. 101-629, § 5(c)(2), substituted "The Secretary may initiate the reclassification of a device classified into class III under paragraph (1) of this subsection or the manufacturer" for "The manufacturer".

Subsec. (*l*)(5). Pub. L. 101-629, § 4(b)(2), added par. (5).

Subsec. (m). Pub. L. 101-629, § 14(a), added subsec. (m).

EFFECTIVE DATE OF 1990 AMENDMENT

Section 14(b) of Pub. L. 101-629 provided that: "Subsection (m) of section 520 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(m)], as added by the amendment made by subsection (a), shall take effect on the effective date of the regulations issued by the Secretary under paragraph (6) of such subsection."

REPORT ON HUMANITARIAN DEVICE EXEMPTIONS

Section 14(c) of Pub. L. 101-629 provided that: "Within 4 years after the issuance of regulations under section 520(m)(6) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 360j(m)(6)], as added by the amendment made by subsection (a), the Secretary of Health and Human Services shall report to the Congress (1) on the types of devices exempted under such section, (2) an evaluation of the effects of such section, and (3) a recommendation on extension of the section."

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the General Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 331, 333, 351, 352, 353, 360c, 360d, 360e, 360g, 360l, 374, 381, 383 of this title.

§ 360*l*. Postmarket surveillance

(a) In general

(1) Required surveillance

The Secretary shall require a manufacturer to conduct postmarket surveillance for any device of the manufacturer first introduced or delivered for introduction into interstate commerce after January 1, 1991, that—

(A) is a permanent implant the failure of which may cause serious, adverse health consequences or death,

(B) is intended for a use in supporting or sustaining human life, or

(C) potentially presents a serious risk to human health.

(2) Discretionary surveillance

The Secretary may require a manufacturer to conduct postmarket surveillance for a device of the manufacturer if the Secretary determines that postmarket surveillance of the device is necessary to protect the public health or to provide safety or effectiveness data for the device.

(b) Surveillance approval

Each manufacturer required to conduct a surveillance of a device under subsection (a) of this section shall, within 30 days of the first introduction or delivery for introduction of such device into interstate commerce submit, for the approval of the Secretary, a protocol for the required surveillance. The Secretary, within 60 days of the receipt of such protocol, shall determine if the principal investigator proposed to be used in the surveillance has sufficient qualifications and experience to conduct such surveillance and if such protocol will result in collection of useful data or other information necessary to protect the public health and to provide safety and effectiveness information for the device. The Secretary may not approve such a protocol until it has been reviewed by an appropriately qualified scientific and technical review committee established by the Secretary.

(June 25, 1938, ch. 675, § 522, as added Nov. 28, 1990, Pub. L. 101-629, § 10, 104 Stat. 4521.)

PART B—DRUGS FOR RARE DISEASES OR CONDITIONS

§ 360ee. Grants and contracts for development of drugs for rare diseases and conditions

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 343 of this title; title 42 section 236.

PART C—ELECTRONIC PRODUCT RADIATION CONTROL

CODIFICATION

This part was classified to subpart 3 (§ 263b et seq.) of part F of subchapter II of chapter 6A of Title 42, The Public Health and Welfare, prior to its renumbering by Pub. L. 101-629, § 19(a)(4), Nov. 28, 1990, 104 Stat. 4530.

PART REFERRED TO IN OTHER SECTIONS

This part is referred to in title 15 section 2080.

§ 360gg. Repealed. Pub. L. 101-629, § 19(a)(3), Nov. 28, 1990, 104 Stat. 4530

Section, act June 25, 1938, ch. 675, § 530, formerly act July 1, 1944, ch. 373, title III, § 354, as added Oct. 18, 1966, Pub. L. 90-602, § 2(3), 82 Stat. 1173; renumbered § 530 of act June 25, 1938, and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (4), 104 Stat. 4529, 4530, set forth Congressional declaration of purpose.

Section was classified to section 263b of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

§ 360hh. Definitions

As used in this part—

(1) the term "electronic product radiation" means—

(A) any ionizing or non-ionizing electromagnetic or particulate radiation, or

(B) any sonic, infrasonic, or ultrasonic wave, which is emitted from an electronic product as the result of the operation of an electronic circuit in such product;

(2) the term "electronic product" means (A) any manufactured or assembled product which, when in operation, (i) contains or acts as part of an electronic circuit and (ii) emits (or in the absence of effective shielding or other controls would emit) electronic product radiation, or (B) any manufactured or assembled article which is intended for use as a component, part, or accessory of a product described in clause (A) and which when in operation emits (or in the absence of effective shielding or other controls would emit) such radiation;

(3) the term "manufacturer" means any person engaged in the business of manufacturing, assembling, or importing of electronic products;

(4) the term "commerce" means (A) commerce between any place in any State and any place outside thereof; and (B) commerce wholly within the District of Columbia; and

(5) the term "State" includes the District of Columbia, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, Guam, and American Samoa.

(June 25, 1938, ch. 675, § 531, formerly act July 1, 1944, ch. 373, title III, § 531, formerly § 355, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1174, and amended Oct. 12, 1976, Pub. L. 94-484, title IX, § 905(b)(1), 90 Stat. 2325; renumbered § 531 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263c of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263c of Title 42, The Public Health and Welfare, as this section.

Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" in introductory provisions.

1976—Par. (5). Pub. L. 94-464 defined "State" to include Northern Mariana Islands.

SHORT TITLE

For short title of Pub. L. 90-602, which enacted provisions now comprising this part (§§ 360gg to 360ss), as the "Radiation Control for Health and Safety Act of 1968", see section 1 of Pub. L. 90-602, set out as a Short Title of 1968 Amendments note under section 301 of this title.

TRANSFER OF SUBPART; CONSTRUCTION

Section 19(c) of Pub. L. 101-629 provided that: "The transfer of subpart 3 of part F of title III of the Public Health Service Act [42 U.S.C. 263b et seq.] to the Federal Food, Drug, and Cosmetic Act [this chapter] does not change the application of the requirements of such subpart and such Act to electronic products which were in effect on the date of the enactment of this Act [Nov. 28, 1990]."

DEFINITION OF "SECRETARY" AND "DEPARTMENT"

Section 3 of Pub. L. 90-602, as amended Pub. L. 96-86, title V, § 509(b), Oct. 17, 1979, 93 Stat. 695, provided that: "As used in the amendments made by section 2 of this Act [enacting provisions now comprising sections 360gg to 360ss of this title], except when otherwise specified, the term 'Secretary' means the Secretary of Health and Human Services, and the term 'Department' means the Department of Health and Human Services."

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Section 4 of Pub. L. 90-602 provided that: "The amendments made by section 2 of this Act [enacting provisions now comprising sections 360gg to 360ss of this title] shall not be construed as superseding or limiting the functions, under any other provision of law, of any officer or agency of the United States."

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360kk of this title; title 15 section 2080.

§ 360ii. Program of control

(a) Establishment

The Secretary shall establish and carry out an electronic product radiation control program designed to protect the public health and safety from electronic product radiation. As a part of such program, he shall—

(1) pursuant to section 360kk of this title, develop and administer performance standards for electronic products;

(2) plan, conduct, coordinate, and support research, development, training, and oper-

ational activities to minimize the emissions of and the exposure of people to, unnecessary electronic product radiation;

(3) maintain liaison with and receive information from other Federal and State departments and agencies with related interests, professional organizations, industry, industry and labor associations, and other organizations on present and future potential electronic product radiation;

(4) study and evaluate emissions of, and conditions of exposure to, electronic product radiation and intense magnetic fields;

(5) develop, test, and evaluate the effectiveness of procedures and techniques for minimizing exposure to electronic product radiation; and

(6) consult and maintain liaison with the Secretary of Commerce, the Secretary of Defense, the Secretary of Labor, the Atomic Energy Commission, and other appropriate Federal departments and agencies on (A) techniques, equipment, and programs for testing and evaluating electronic product radiation, and (B) the development of performance standards pursuant to section 360kk of this title to control such radiation emissions.

(b) Powers of Secretary

In carrying out the purposes of subsection (a) of this section, the Secretary is authorized to—

(1)(A) collect and make available, through publications and other appropriate means, the results of, and other information concerning, research and studies relating to the nature and extent of the hazards and control of electronic product radiation; and (B) make such recommendations relating to such hazards and control as he considers appropriate;

(2) make grants to public and private agencies, organizations, and institutions, and to individuals for the purposes stated in paragraphs (2), (4), and (5) of subsection (a) of this section;

(3) contract with public or private agencies, institutions, and organizations, and with individuals, without regard to section 3324 of title 31 and section 5 of title 41; and

(4) procure (by negotiation or otherwise) electronic products for research and testing purposes, and sell or otherwise dispose of such products.

(c) Record keeping

(1) Each recipient of assistance under this part pursuant to grants or contracts entered into under other than competitive bidding procedures shall keep such records as the Secretary shall prescribe, including records which fully disclose the amount and disposition by such recipient of the proceeds of such assistance, the total cost of the project or undertaking in connection with which such assistance is given or used, and the amount of that portion of the cost of the project or undertaking supplied by other sources, and such other records as will facilitate an effective audit.

(2) The Secretary and the Comptroller General of the United States, or any of their duly authorized representatives, shall have access for the purpose of audit and examination to any books, documents, papers, and records of the recipients that are pertinent to the grants or contracts entered into under this part under other than competitive bidding procedures.

(June 25, 1938, ch. 675, § 532, formerly act July 1, 1944, ch. 373, title III, § 532, formerly § 356, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1174, and renumbered § 532 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(A), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263d of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263d of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(1), (6). Pub. L. 101-629, § 19(a)(2)(A)(i), substituted "section 360kk" for "section 263f".

Subsec. (b)(3). Pub. L. 101-629, § 19(a)(2)(A)(ii), substituted reference to section 3324 of title 31 for reference to section 3648 of the Revised Statutes (31 U.S.C. 529).

Subsec. (c)(1), (2). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

TRANSFER OF FUNCTIONS

Atomic Energy Commission abolished and functions transferred by sections 5814 and 5841 of Title 42, The Public Health and Welfare. See also Transfer of Functions notes set out under those sections.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law or any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360jj. Studies by Secretary

(a) Report to Congress

The Secretary shall conduct the following studies, and shall make a report or reports of the results of such studies to the Congress on or before January 1, 1970, and from time to time thereafter as he may find necessary, together with such recommendations for legislation as he may deem appropriate:

(1) A study of present State and Federal control of health hazards from electronic product radiation and other types of ionizing radiation, which study shall include, but not be limited to—

(A) control of health hazards from radioactive materials other than materials regulated under the Atomic Energy Act of 1954 [42 U.S.C. 2011 et seq.];

(B) any gaps and inconsistencies in present controls;

(C) the need for controlling the sale of certain used electronic products, particularly antiquated X-ray equipment, without upgrading such products to meet the standards for new products or separate standards for used products;

(D) measures to assure consistent and effective control of the aforementioned health hazards;

(E) measures to strengthen radiological health programs of State governments; and

(F) the feasibility of authorizing the Secretary to enter into arrangements with individual States or groups of States to define their respective functions and responsibilities for the control of electronic product radiation and other ionizing radiation;

(2) A study to determine the necessity for the development of standards for the use of nonmedical electronic products for commercial and industrial purposes; and

(3) A study of the development of practicable procedures for the detection and measurement of electronic product radiation which may be emitted from electronic products manufactured or imported prior to the effective date of any applicable standard established pursuant to this part.

(b) Participation of other Federal agencies

In carrying out these studies, the Secretary shall invite the participation of other Federal departments and agencies having related responsibilities and interests, State governments—particularly those of States which regulate radioactive materials under section 274 of the Atomic Energy Act of 1954, as amended [42 U.S.C. 2021], and interested professional, labor, and industrial organizations. Upon request from congressional committees interested in these studies, the Secretary shall keep these committees currently informed as to the progress of the studies and shall permit the committees to send observers to meetings of the study groups.

(c) Organization of studies and participation

The Secretary or his designee shall organize the studies and the participation of the invited participants as he deems best. Any dissent from the findings and recommendations of the Secretary shall be included in the report if so requested by the dissenter.

(June 25, 1938, ch. 675, § 533, formerly act July 1, 1944, ch. 373, title III, § 533, formerly § 357, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1176, and renumbered § 533 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530.)

REFERENCES IN TEXT

The Atomic Energy Act of 1954, referred to in subsec. (a)(1)(A), is act Aug. 30, 1954, ch. 1073, § 1, 68 Stat. 921, as amended, which is classified generally to chapter 23 (§ 2011 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 2011 of Title 42 and Tables.

CODIFICATION

Section was classified to section 263e of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263e of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(3). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360kk. Performance standards for electronic products

(a) Promulgation of regulations

(1) The Secretary shall by regulation prescribe performance standards for electronic products to control the emission of electronic product radiation from such products if he determines that such standards are necessary for the protection of the public health and safety. Such standards may include provisions for the testing of such products and the measurement of their electronic product radiation emissions, may require the attachment of warning signs and labels, and may require the provision of instructions for the installation, operation, and use of such products. Such standards may be prescribed from time to time whenever such determinations are made, but the first of such standards shall be prescribed prior to January 1, 1970. In the development of such standards, the Secretary shall consult with Federal and State departments and agencies having related responsibilities or interests and with appropriate professional organizations and interested persons, including representatives of industries and labor organizations which would be affected by such standards, and shall give consideration to—

(A) the latest available scientific and medical data in the field of electronic product radiation;

(B) the standards currently recommended by (i) other Federal agencies having responsibilities relating to the control and measurement of electronic product radiation, and (ii) public or private groups having an expertise in the field of electronic product radiation;

(C) the reasonableness and technical feasibility of such standards as applied to a particular electronic product;

(D) the adaptability of such standards to the need for uniformity and reliability of testing and measuring procedures and equipment; and

(E) in the case of a component, or accessory described in paragraph (2)(B) of section 360hh of this title, the performance of such article in the manufactured or assembled product for which it is designed.

(2) The Secretary may prescribe different and individual performance standards, to the extent appropriate and feasible, for different electronic products so as to recognize their different operating characteristics and uses.

(3) The performance standards prescribed under this section shall not apply to any electronic product which is intended solely for export if (A) such product and the outside of any shipping container used in the export of such product are labeled or tagged to show that such product is intended for export, and (B) such product meets all the applicable requirements of the country to which such product is intended for export.

(4) The Secretary may by regulation amend or revoke any performance standard prescribed under this section.

(5) The Secretary may exempt from the provisions of this section any electronic product intended for use by departments or agencies of the United States provided such department or agency has prescribed procurement specifications governing emissions of electronic product radiation and provided further that such product is of a type used solely or predominantly by departments or agencies of the United States.

(b) Administrative procedure

The provisions of subchapter II of chapter 5 of title 5 (relating to the administrative procedure for rulemaking), and of chapter 7 of title 5 (relating to judicial review), shall apply with respect to any regulation prescribing, amending, or revoking any standard prescribed under this section.

(c) Publication in Federal Register

Each regulation prescribing, amending, or revoking a standard shall specify the date on which it shall take effect which, in the case of any regulation prescribing, or amending any standard, may not be sooner than one year or not later than two years after the date on which such regulation is issued, unless the Secretary finds, for good cause shown, that an earlier or later effective date is in the public interest and publishes in the Federal Register his reason for such finding, in which case such earlier or later date shall apply.

(d) Judicial review

(1) In a case of actual controversy as to the validity of any regulation issued under this section prescribing, amending, or revoking a performance standard, any person who will be adversely affected by such regulation when it is effective may at any time prior to the sixtieth day after such regulation is issued file a petition with the United States court of appeals for the circuit wherein such person resides or has his principal place of business, for a judicial review of such regulation. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based the regulation, as provided in section 2112 of title 28.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendations, if any, for the modification or setting aside of his original regulation, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to review the regulation in accordance with chapter 7 of title 5 and to grant appropriate relief as provided in such chapter.

(4) The judgment of the court affirming or setting aside, in whole or in part, any such regulation of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28.

(5) Any action instituted under this subsection shall survive, notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not substitution for any other remedies provided by law.

(e) Availability of record

A certified copy of the transcript of the record and administrative proceedings under this section shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, exclusion of imports, or other proceeding arising under or in respect of this part irrespective of whether proceedings with respect to the regulation have previously been initiated or become final under this section.

(f) Technical Electronic Product Radiation Safety Standards Committee

(1)(A) The Secretary shall establish a Technical Electronic Product Radiation Safety Standards Committee (hereafter in this part referred to as the "Committee") which he shall consult before prescribing any standard under this section. The Committee shall be appointed by the Secretary, after consultation with public and private agencies concerned with the technical aspect of electronic product radiation safety, and shall be composed of fifteen members each of whom shall be technically qualified by training and experience in one or more fields of science or engineering applicable to electronic product radiation safety, as follows:

(i) Five members shall be selected from governmental agencies, including State and Federal Governments;

(ii) Five members shall be selected from the affected industries after consultation with industry representatives; and

(iii) Five members shall be selected from the general public, of which at least one shall be a representative of organized labor.

(B) The Committee may propose electronic product radiation safety standards to the Secretary for his consideration. All proceedings of the Committee shall be recorded and the record of each such proceeding shall be available for public inspection.

(2) Payments to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42 [1] shall not render members of the

[1] See References in Text note below.

Committee officers or employees of the United States for any purpose.

(g) Review and evaluation

The Secretary shall review and evaluate on a continuing basis testing programs carried out by industry to assure the adequacy of safeguards against hazardous electronic product radiation and to assure that electronic products comply with standards prescribed under this section.

(h) Product certification

Every manufacturer of an electronic product to which is applicable a standard in effect under this section shall furnish to the distributor or dealer at the time of delivery of such product, in the form of a label or tag permanently affixed to such product or in such manner as approved by the Secretary, the certification that such product conforms to all applicable standards under this section. Such certification shall be based upon a test, in accordance with such standard, of the individual article to which it is attached or upon a testing program which is in accord with good manufacturing practice and which has not been disapproved by the Secretary (in such manner as he shall prescribe by regulation) on the grounds that it does not assure the adequacy of safeguards against hazardous electronic product radiation or that it does not assure that electronic products comply with the standards prescribed under this section.

(June 25, 1938, ch. 675, § 534, formerly act July 1, 1944, ch. 373, title III, § 534, formerly § 358, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1177, and amended Oct. 30, 1970, Pub. L. 91-515, title VI, § 601(b)(2), (3), 84 Stat. 1311; renumbered § 534 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(B), (3), (4), 104 Stat. 4529, 4530.)

REFERENCES IN TEXT

Section 210 of title 42, referred to in subsec. (f)(2), was in the original "section 208 of this Act" and has been translated as reading "section 208 of the Public Health Service Act" to reflect the probable intent of Congress and the transfer of this section from the Public Health Service Act by Pub. L. 101-629.

CODIFICATION

Section was classified to section 263f of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263f of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(1)(E). Pub. L. 101-629, § 19(a)(2)(B), substituted "section 360hh" for "section 263c".

Subsecs. (e), (f)(1)(A). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

1970—Subsec. (f)(2). Pub. L. 91-515 struck out provisions related to payment of compensation and travel expenses of members of the Committee who are not officers or employees of the United States, and substituted "to members of the Committee who are not officers or employees of the United States pursuant to subsection (c) of section 210 of title 42" for "under this subsection".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360ii, 360*ll*, 360mm, 360nn, 360oo, 360pp, 360ss of this title.

§ 360*ll*. Notification of defects in and repair or replacement of electronic products

(a) Notification; exemption

(1) Every manufacturer of electronic products who discovers that an electronic product produced, assembled, or imported by him has a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, or that an electronic product produced, assembled, or imported by him on or after the effective date of an applicable standard prescribed pursuant to section 360kk of this title fails to comply with such standard, shall immediately notify the Secretary of such defect or failure to comply if such product has left the place of manufacture and shall (except as authorized by paragraph (2)) with reasonable promptness furnish notification of such defect or failure to the persons (where known to the manufacturer) specified in subsection (b) of this section.

(2) If, in the opinion of such manufacturer, the defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he may, at the time of giving notice to the Secretary of such defect or failure to comply, apply to the Secretary for an exemption from the requirement of notice to the persons specified in subsection (b) of this section. If such application states reasonable grounds for such exemption, the Secretary shall afford such manufacturer an opportunity to present his views and evidence in support of the application, the burden of proof being on the manufacturer. If, after such presentation, the Secretary is satisfied that such defect or failure to comply is not such as to create a significant risk of injury, including genetic injury, to any person, he shall exempt such manufacturer from the requirement of notice to the persons specified in subsection (b) of this section and from the requirements of repair or replacement imposed by subsection (f) of this section.

(b) Method of notification

The notification (other than to the Secretary) required by paragraph (1) of subsection (a) of this section shall be accomplished—

(1) by certified mail to the first purchaser of such product for purposes other than resale, and to any subsequent transferee of such product; and

(2) by certified mail or other more expeditious means to the dealers or distributors of such manufacturer to whom such product was delivered.

(c) Requisite elements of notification

The notifications required by paragraph (1) of subsection (a) of this section shall contain a clear description of such defect or failure to comply with an applicable standard, an evaluation of the hazard reasonably related to such defect or failure to comply, and a statement of the measures to be taken to repair such defect. In the case of a notification to a person referred to in subsection (b) of this section, the notification shall also advise the person of his rights under subsection (f) of this section.

(d) Copies to Secretary of communications by manufacturers to dealers or distributors regarding defects

Every manufacturer of electronic products shall furnish to the Secretary a true or representative copy of all notices, bulletins, and other communications to the dealers or distributors of such manufacturer or to purchasers (or subsequent transferees) of electronic products of such manufacturer regarding any such defect in such product or any such failure to comply with a standard applicable to such product. The Secretary shall disclose to the public so much of the information contained in such notice or other information obtained under section 360nn of this title as he deems will assist in carrying out the purposes of this part, but he shall not disclose any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18 unless he determines that it is necessary to carry out the purposes of this part.

(e) Notice from Secretary to manufacturer of defects or failure to comply with standards

If through testing, inspection, investigation, or research carried out pursuant to this part, or examination of reports submitted pursuant to section 360nn of this title, or otherwise, the Secretary determines that any electronic product—

(1) does not comply with an applicable standard prescribed pursuant to section 360kk of this title; or

(2) contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation;

he shall immediately notify the manufacturer of such product of such defect or failure to comply. The notice shall contain the findings of the Secretary and shall include all information upon which the findings are based. The Secretary shall afford such manufacturer an opportunity to present his views and evidence in support thereof, to establish that there is no failure of compliance or that the alleged defect does not exist or does not relate to safety of use of the product by reason of the emission of such radiation hazard. If after such presentation by the manufacturer the Secretary determines that such product does not comply with an applicable standard prescribed pursuant to section 360kk of this title, or that it contains a defect which relates to the safety of use of such product by reason of the emission of electronic product radiation, the Secretary shall direct the manufacturer to furnish the notification specified in subsection (c) of this section to the persons specified in paragraphs (1) and (2) of subsection (b) of this section (where known to the manufacturer), unless the manufacturer has applied for an exemption from the requirement of such notification on the ground specified in paragraph (2) of subsection (a) of this section and the Secretary is satisfied that such noncompliance or defect is not such as to create a significant risk of injury, including genetic injury, to any person.

(f) Correction of defects

If any electronic product is found under subsection (a) or (e) of this section to fail to comply with an applicable standard prescribed under this part or to have a defect which relates to the safety of use of such product, and the notification specified in subsection (c) of this section is required to be furnished on account of such failure or defect, the manufacturer of such product shall (1) without charge, bring such product into conformity with such standard or remedy such defect and provide reimbursement for any expenses for transportation of such product incurred in connection with having such product brought into conformity or having such defect remedied, (2) replace such product with a like or equivalent product which complies with each applicable standard prescribed under this part and which has no defect relating to the safety of its use, or (3) make a refund of the cost of such product. The manufacturer shall take the action required by this subsection in such manner, and with respect to such persons, as the Secretary by regulations shall prescribe.

(g) Effective date

This section shall not apply to any electronic product that was manufactured before October 18, 1968.

(June 25, 1938, ch. 675, § 535, formerly act July 1, 1944, ch. 373, title III, § 535, formerly § 359, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1180, and renumbered § 535 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(C), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263g of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263g of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(1). Pub. L. 101-629, § 19(a)(2)(C)(i), substituted "section 360kk" for "section 263f".

Subsec. (d). Pub. L. 101-629, § 19(a)(1)(B), (2)(C)(ii), substituted "section 360nn" for "section 263i" and "this part" for "this subpart" in two places.

Subsec. (e). Pub. L. 101-629, § 19(a)(1)(B), (2)(C), substituted "this part" for "this subpart" and "section 360nn" for "section 263i" in introductory provisions and "section 360kk" for "section 263f" in par. (1) and concluding provisions.

Subsec. (f). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" in two places.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provi-

sion of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360nn, 360oo of this title.

§ 360mm. Imports

(a) Refusal of admission to noncomplying electronic products

Any electronic product offered for importation into the United States which fails to comply with an applicable standard prescribed under this part, or to which is not affixed a certification in the form of a label or tag in conformity with section 360kk(h) of this title shall be refused admission into the United States. The Secretary of the Treasury shall deliver to the Secretary of Health and Human Services, upon the latter's request, samples of electronic products which are being imported or offered for import into the United States, giving notice thereof to the owner or consignee, who may have a hearing before the Secretary of Health and Human Services. If it appears from an examination of such samples or otherwise that any electronic product fails to comply with applicable standards prescribed pursuant to section 360kk of this title, then, unless subsection (b) of this section applies and is complied with, (1) such electronic product shall be refused admission, and (2) the Secretary of the Treasury shall cause the destruction of such electronic product unless such article is exported, under regulations prescribed by the Secretary of the Treasury, within 90 days after the date of notice of refusal of admission or within such additional time as may be permitted by such regulations.

(b) Bond

If it appears to the Secretary of Health and Human Services that any electronic product refused admission pursuant to subsection (a) of this section can be brought into compliance with applicable standards prescribed pursuant to section 360kk of this title, final determination as to admission of such electronic product may be deferred upon filing of timely written application by the owner or consignee and the execution by him of a good and sufficient bond providing for the payment of such liquidated damages in the event of default as the Secretary of Health and Human Services may by regulation prescribe. If such application is filed and such bond is executed the Secretary of Health and Human Services may, in accordance with rules prescribed by him, permit the applicant to perform such operations with respect to such electronic product as may be specified in the notice of permission.

(c) Liability of owner or consignee for expenses connected with refusal of admission

All expenses (including travel, per diem or subsistence, and salaries of officers or employees of the United States) in connection with the destruction provided for in subsection (a) of this section and the supervision of operations provided for in subsection (b) of this section, and all expenses in connection with the storage, cartage, or labor with respect to any electronic product refused admission pursuant to subsection (a) of this section, shall be paid by the owner or consignee, and, in event of default, shall constitute a lien against any future importations made by such owner or consignee.

(d) Designation of agent for purposes of service

It shall be the duty of every manufacturer offering an electronic product for importation into the United States to designate in writing an agent upon whom service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made for and on behalf of said manufacturer, and to file such designation with the Secretary, which designation may from time to time be changed by like writing, similarly filed. Service of all administrative and judicial processes, notices, orders, decisions, and requirements may be made upon said manufacturer by service upon such designated agent at his office or usual place of residence with like effect as if made personally upon said manufacturer, and in default of such designation of such agent, service of process, notice, order, requirement, or decision in any proceeding before the Secretary or in any judicial proceeding for enforcement of this part or any standards prescribed pursuant to this part may be made by posting such process, notice, order, requirement, or decision in the Office of the Secretary or in a place designated by him by regulation.

(June 25, 1938, ch. 675, § 536, formerly act July 1, 1944, ch. 373, title III, § 536, formerly § 360, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1181, and amended Oct. 17, 1979, Pub. L. 96-88, title V, § 509(b), 93 Stat. 695; renumbered § 536 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(D), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263h of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263h of Title 42, The Public Health and Welfare, as this section.

Subsec. (a). Pub. L. 101-629, § 19(a)(1)(B), (2)(D), substituted "this part" for "this subpart", "section 360kk(h)" for "section 263f(h)", and "section 360kk" for "section 263f".

Subsec. (b). Pub. L. 101-629, § 19(a)(2)(D), substituted "section 360kk" for "section 263f".

Subsec. (d). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" in two places.

CHANGE OF NAME

"Secretary of Health and Human Services" substituted for "Secretary of Health, Education, and Welfare" in subsecs. (a) and (b) pursuant to section 509(b) of Pub. L. 96-88 which is classified to section 3508(b) of Title 20, Education.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360nn. Inspection, records, and reports

(a) Inspection of premises

If the Secretary finds for good cause that the methods, tests, or programs related to electronic product radiation safety in a particular factory, warehouse, or establishment in which electronic products are manufactured or held, may not be adequate or reliable, officers or employees duly designated by the Secretary, upon presenting appropriate credentials and a written notice to the owner, operator, or agent in charge, are thereafter authorized (1) to enter, at reasonable times, any area in such factory, warehouse, or establishment in which the manufacturer's tests (or testing programs) required by section 360kk(h) of this title are carried out, and (2) to inspect, at reasonable times and within reasonable limits and in a reasonable manner, the facilities and procedures within such area which are related to electronic product radiation safety. Each such inspection shall be commenced and completed with reasonable promptness. In addition to other grounds upon which good cause may be found for purposes of this subsection, good cause will be considered to exist in any case where the manufacturer has introduced into commerce any electronic product which does not comply with an applicable standard prescribed under this part and with respect to which no exemption from the notification requirements has been granted by the Secretary under section 360*ll*(a)(2) or 360*ll*(e) of this title.

(b) Record keeping

Every manufacturer of electronic products shall establish and maintain such records (including testing records), make such reports, and provide such information, as the Secretary may reasonably require to enable him to determine whether such manufacturer has acted or is acting in compliance with this part and standards prescribed pursuant to this part and shall, upon request of an officer or employee duly designated by the Secretary, permit such officer or employee to inspect appropriate books, papers, records, and documents relevant to determining whether such manufacturer has acted or is acting in compliance with standards prescribed pursuant to this part.

(c) Disclosure of technical data

Every manufacturer of electronic products shall provide to the Secretary such performance data and other technical data related to safety as may be required to carry out the purposes of this part. The Secretary is authorized to require the manufacturer to give such notification of such performance and technical data at the time of original purchase to the ultimate purchaser of the electronic product, as he determines necessary to carry out the purposes of this part after consulting with the affected industry.

(d) Public nature of reports

Accident and investigation reports made under this part by any officer, employee, or agent of the Secretary shall be available for use in any civil, criminal, or other judicial proceeding arising out of such accident. Any such officer, employee, or agent may be required to testify in such proceedings as to the facts developed in such investigations. Any such report shall be made available to the public in a manner which need not identify individuals. All reports on research projects, demonstration projects, and other related activities shall be public information.

(e) Trade secrets

The Secretary or his representative shall not disclose any information reported to or otherwise obtained by him, pursuant to subsection (a) or (b) of this section, which concerns any information which contains or relates to a trade secret or other matter referred to in section 1905 of title 18, except that such information may be disclosed to other officers or employees of the Department and of other agencies concerned with carrying out this part or when relevant in any proceeding under this part. Nothing in this section shall authorize the withholding of information by the Secretary, or by any officers or employees under his control, from the duly authorized committees of the Congress.

(f) Information required to identify and locate first purchasers of electronic products

The Secretary may by regulation (1) require dealers and distributors of electronic products, to which there are applicable standards prescribed under this part and the retail prices of which is not less than $50, to furnish manufacturers of such products such information as may be necessary to identify and locate, for purposes of section 360*ll* of this title, the first purchasers of such products for purposes other than resale, and (2) require manufacturers to preserve such information. Any regulation establishing a requirement pursuant to clause (1) of the preceding sentence shall (A) authorize such dealers and distributors to elect, in lieu of immediately furnishing such information to the manufacturer, to hold and preserve such information until advised by the manufacturer or Secretary that such information is needed by the manufacturer for purposes of section 360*ll* of this title, and (B) provide that the dealer or distributor shall, upon making such election, give prompt notice of such election (together with information identifying the notifier and the product) to the manufacturer and shall, when advised by the manufacturer or Secretary, of the need therefor for the purposes of section 360*ll* of this title, immediately furnish the manufacturer with the required information. If a dealer or distributor discontinues the dealing in or distribution of electronic products, he shall turn the information over to the manufacturer. Any manufacturer receiving information pursuant to this subsection concerning first purchasers of products for purposes other than resale shall treat it as confidential and may use it only if necessary for the purpose of notifying persons pursuant to section 360*ll*(a) of this title.

(June 25, 1938, ch. 675, § 537, formerly act July 1, 1944, ch. 373, title III, § 537, formerly § 360A, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1182; renumbered § 537 and amended Nov.

28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(E), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263*l* of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263*l* of Title 42, The Public Health and Welfare, as this section.

Subsec. (a). Pub. L. 101-629, § 19(a)(1)(B), (2)(E), substituted "section 360kk(h)" for "section 263f(h)", "this part" for "this subpart", and "section 360*ll*(a)(2) or 360*ll*(e)" for "section 263g(a)(2) or 263g(e)".

Subsecs. (b) to (e). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" wherever appearing.

Subsec. (f). Pub. L. 101-629, § 19(a)(1)(B), (2)(E)(ii), substituted "this part" for "this subpart", "section 360*ll*" for "section 263g" in three places, and "section 360*ll*(a)" for "section 263g(a)".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 360*ll*, 360*oo* of this title.

§ 360*oo*. Prohibited acts

(a) It shall be unlawful—

(1) for any manufacturer to introduce, or to deliver for introduction, into commerce, or to import into the United States, any electronic product which does not comply with an applicable standard prescribed pursuant to section 360kk of this title;

(2) for any person to fail to furnish any notification or other material or information required by section 360*ll* or 360nn of this title; or to fail to comply with the requirements of section 360*ll*(f) of this title;

(3) for any person to fail or to refuse to establish or maintain records required by this part or to permit access by the Secretary or any of his duly authorized representatives to, or the copying of, such records, or to permit entry or inspection, as required by or pursuant to section 360nn of this title;

(4) for any person to fail or to refuse to make any report required pursuant to section 360nn(b) of this title or to furnish or preserve any information required pursuant to section 360nn(f) of this title; or

(5) for any person (A) to fail to issue a certification as required by section 360kk(h) of this title, or (B) to issue such a certification when such certification is not based upon a test or testing program meeting the requirements of section 360kk(h) of this title or when the issuer, in the exercise of due care, would have reason to know that such certification is false or misleading in a material respect.

(b) The Secretary may exempt any electronic product, or class thereof, from all or part of subsection (a) of this section, upon such conditions as he may find necessary to protect the public health or welfare, for the purpose of research, investigations, studies, demonstrations, or training, or for reasons of national security.

(June 25, 1938, ch. 675, § 538, formerly act July 1, 1944, ch. 373, title III, § 538, formerly § 360B, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1184, and renumbered § 538 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(F), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263*j* of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263*j* of Title 42, The Public Health and Welfare, as this section.

Subsec. (a)(1). Pub. L. 101-629, § 19(a)(2)(F)(i), substituted "section 360kk" for "section 263f".

Subsec. (a)(2). Pub. L. 101-629, § 19(a)(2)(F)(ii), (iii), substituted "section 360*ll* or 360nn" for "section 263g or 263*l*" and "section 360*ll*(f)" for "section 263g(f)".

Subsec. (a)(3). Pub. L. 101-629, § 19(a)(1)(B), (2)(F)(iii), substituted "this part" for "this subpart" and "section 360nn" for "section 263*l*".

Subsec. (a)(4). Pub. L. 101-629, § 19(a)(2)(F)(iii), substituted "section 360nn(b)" for "section 263*l*(b)" and "section 360nn(f)" for "section 263*l*(f)".

Subsec. (a)(5). Pub. L. 101-629, § 19(a)(2)(F)(i), substituted "section 360kk(h)" for "section 263f(h)" in two places.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360pp of this title.

§ 360pp. Enforcement

(a) Jurisdiction of courts

The district courts of the United States shall have jurisdiction, for cause shown, to restrain violations of section 360*oo* of this title and to restrain dealers and distributors of electronic products from selling or otherwise disposing of electronic products which do not conform to an applicable standard prescribed pursuant to section 360kk of this title except when such products are disposed of by returning them to the distributor or manufacturer from whom they were obtained. The district courts of the United States shall also have jurisdiction in accordance with section 1355 of title 28 to enforce the provisions of subsection (b) of this section.

(b) Penalties

(1) Any person who violates section 360*oo* of this title shall be subject to a civil penalty of not more than $1,000. For purposes of this subsection, any such violation shall with respect to each electronic product involved, or with respect to each act or omission made unlawful by section 360*oo* of this title, constitute a separate violation, except that the maximum civil penal-

ty imposed on any person under this subsection for any related series of violations shall not exceed $300,000.

(2) Any such civil penalty may on application be remitted or mitigated by the Secretary. In determining the amount of such penalty, or whether it should be remitted or mitigated and in what amount, the appropriateness of such penalty to the size of the business of the person charged and the gravity of the violation shall be considered. The amount of such penalty, when finally determined, may be deducted from any sums owing by the United States to the person charged.

(c) Venue; process

Actions under subsections (a) and (b) of this section may be brought in the district court of the United States for the district wherein any act or omission or transaction constituting the violation occurred, or in such court for the district where the defendant is found or transacts business, and process in such cases may be served in any other district of which the defendant is an inhabitant or wherever the defendant may be found.

(d) Warnings

Nothing in this part shall be construed as requiring the Secretary to report for the institution of proceedings minor violations of this part whenever he believes that the public interest will be adequately served by a suitable written notice or warning.

(e) Compliance with regulations

Except as provided in the first sentence of section 360ss of this title, compliance with this part or any regulations issued thereunder shall not relieve any person from liability at common law or under statutory law.

(f) Additional remedies

The remedies provided for in this part shall be in addition to and not in substitution for any other remedies provided by law.

(June 25, 1938, ch. 675, § 539, formerly act July 1, 1944, ch. 373, title III, § 539, formerly § 360C, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1184, and renumbered § 539 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(G), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263k of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263k of Title 42, The Public Health and Welfare, as this section.

Subsec. (a). Pub. L. 101-629, § 19(a)(2)(G)(i), (ii), substituted "section 360oo" for "section 263j" and "section 360kk" for "section 263f".

Subsec. (b)(1). Pub. L. 101-629, § 19(a)(2)(G)(ii), substituted "section 360oo" for "section 263j" in two places.

Subsec. (d). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" in two places.

Subsec. (e). Pub. L. 101-629, § 19(a)(1)(B), (2)(G)(iii), substituted "section 360ss" for "section 263n" and "this part" for "this subpart".

Subsec. (f). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360qq. Annual report

(a) The Secretary shall prepare and submit to the President for transmittal to the Congress on or before April 1 of each year a comprehensive report on the administration of this part for the preceding calendar year. Such report shall include—

(1) a thorough appraisal (including statistical analyses, estimates, and long-term projections) of the incidence of biological injury and effects, including genetic effects, to the population resulting from exposure to electronic product radiation, with a breakdown, insofar as practicable, among the various sources of such radiation;

(2) a list of Federal electronic product radiation control standards prescribed or in effect in such year, with identification of standards newly prescribed during such year;

(3) an evaluation of the degree of observance of applicable standards, including a list of enforcement actions, court decisions, and compromises of alleged violations by location and company name;

(4) a summary of outstanding problems confronting the administration of this part in order of priority;

(5) an analysis and evaluation of research activities completed as a result of Government and private sponsorship, and technological progress for safety achieved during such year;

(6) a list, with a brief statement of the issues, of completed or pending judicial actions under this part;

(7) the extent to which technical information was disseminated to the scientific, commercial, and labor community and consumer-oriented information was made available to the public; and

(8) the extent of cooperation between Government officials and representatives of industry and other interested parties in the implementation of this part including a log or summary of meetings held between Government officials and representatives of industry and other interested parties.

(b) The report required by subsection (a) of this section shall contain such recommendations for additional legislation as the Secretary deems necessary to promote cooperation among the several States in the improvement of electronic product radiation control and to strengthen the national electronic product radiation control program.

(June 25, 1938, ch. 675, § 540, formerly act July 1, 1944, ch. 373, title III, § 540, formerly § 360D, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1185, and renumbered § 540 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263*l* of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263*l* of Title 42, The Public Health and Welfare, as this section.

Subsec. (a). Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart" wherever appearing.

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360rr. Federal-State cooperation

The Secretary is authorized (1) to accept from State and local authorities engaged in activities related to health or safety or consumer protection, on a reimbursable basis or otherwise, any assistance in the administration and enforcement of this part which he may request and which they may be able and willing to provide and, if so agreed, may pay in advance or otherwise for the reasonable cost of such assistance, and (2) he may, for the purpose of conducting examinations, investigations, and inspections, commission any officer or employee of any such authority as an officer of the Department.

(June 25, 1938, ch. 675, § 541, formerly act July 1, 1944, ch. 373, title III, § 541, formerly § 360E, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1186, and renumbered § 541 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263m of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263m of Title 42, The Public Health and Welfare, as this section.

Pub. L. 101-629, § 19(a)(1)(B), substituted "this part" for "this subpart".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

§ 360ss. State standards

Whenever any standard prescribed pursuant to section 360kk of this title with respect to an aspect of performance of an electronic product is in effect, no State or political subdivision of a State shall have any authority either to establish, or to continue in effect, any standard which is applicable to the same aspect of performance of such product and which is not identical to the Federal standard. Nothing in this part shall be construed to prevent the Federal Government or the government of any State or political subdivision thereof from establishing a requirement with respect to emission of radiation from electronic products procured for its own use if such requirement imposes a more restrictive standard than that required to comply with the otherwise applicable Federal standard.

(June 25, 1938, ch. 675, § 542, formerly act July 1, 1944, ch. 373, title III, § 542, formerly § 360F, as added Oct. 18, 1968, Pub. L. 90-602, § 2(3), 82 Stat. 1186, and renumbered § 542 and amended Nov. 28, 1990, Pub. L. 101-629, § 19(a)(1)(B), (2)(H), (3), (4), 104 Stat. 4529, 4530.)

CODIFICATION

Section was classified to section 263n of Title 42, The Public Health and Welfare, prior to renumbering by Pub. L. 101-629.

AMENDMENTS

1990—Pub. L. 101-629, § 19(a)(3), (4), renumbered section 263n of Title 42, The Public Health and Welfare, as this section.

Pub. L. 101-629, § 19(a)(1)(B), (2)(H), substituted "section 360kk" for "section 263f" and "this part" for "this subpart".

NONINTERFERENCE WITH OTHER FEDERAL AGENCIES

Enactment of this section not to be construed to supersede or limit the functions under any other provision of law of any officer or agency of the United States, see section 4 of Pub. L. 90-602, set out as a note under section 360hh of this title.

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360pp of this title.

SUBCHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

§ 371. Regulations and hearings

[*See main edition for text of (a) to (d)*]

(e) Procedure for establishment

(1) Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations) shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2) of this subsection, the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

[*See main edition for text of (2) and (3); (f) and (g)*]

(As amended Nov. 8, 1990, Pub. L. 101-535, § 8, 104 Stat. 2365.)

AMENDMENTS

1990—Subsec. (e)(1). Pub. L. 101-535 substituted "Any action for the issuance, amendment, or repeal of any regulation under section 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title, and any action for the amendment or repeal of any definition and standard of identity under section 341 of this title for any dairy product (including products regulated under parts 131, 133 and 135 of title 21, Code of Federal Regulations) or maple sirup (regulated under section 168.140 of title 21, Code of Federal Regulations)" for "Any action for the issuance, amendment, or repeal of any regulation under section 341, 343(j), 344(a), 346, 351(b), or 352(d) or (h) of this title".

CONSTRUCTION OF AMENDMENTS BY PUB. L. 101-535

Amendments by Pub. L. 101-535 not to be construed to alter the authority of the Secretary of Health and Human Services and the Secretary of Agriculture under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), see section 9 of Pub. L. 101-535, set out as a note under section 343 of this title.

§ 375. Publicity

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in section 360h of this title.

§ 376. Listing and certification of color additives for foods, drugs, devices, and cosmetics

REFERENCES IN OTHER LAWS TO GS-16, 17, OR 18 PAY RATES

References in laws to the rates of pay for GS-16, 17, or 18, or to maximum rates of pay under the Oeneral Schedule, to be considered references to rates payable under specified sections of Title 5, Government Organization and Employees, see section 529 [title I, § 101(c)(1)] of Pub. L. 101-509, set out in a note under section 5376 of Title 5.

§ 379b. Consolidated administrative and laboratory facility

(a) Authority

The Secretary, in consultation with the Administrator of the General Services Administration, shall enter into contracts for the design, construction, and operation of a consolidated Food and Drug Administration administrative and laboratory facility.

(b) Awarding of contract

The Secretary shall solicit contract proposals under subsection (a) of this section from interested parties. In awarding contracts under such subsection, the Secretary shall review such proposals and give priority to those alternatives that are the most cost effective for the Federal Government and that allow for the use of donated land, federally owned property, or lease-purchase arrangements. A contract under this subsection shall not be entered into unless such contract results in a net cost savings to the Federal Government over the duration of the contract, as compared to the Government purchase price including borrowing by the Secretary of the Treasury.

(c) Donations

In carrying out this section, the Secretary shall have the power, in connection with real property, buildings, and facilities, to accept on behalf of the Food and Drug Administration gifts or donations of services or property, real or personal, as the Secretary determines to be necessary.

(d) Authorization of appropriations

There are authorized to be appropriated to carry out this section $100,000,000 for fiscal year 1991, and such sums as may be necessary for each of the subsequent fiscal years, to remain available until expended.

(June 25, 1938, ch. 675, § 710, as added Nov. 28, 1990, Pub. L. 101-635, title I, § 101, 104 Stat. 4583.)

§ 379c. Recovery and retention of fees for freedom of information requests

(a) In general

The Secretary, acting through the Commissioner of Food and Drugs, may—

(1) set and charge fees, in accordance with section 552(a)(4)(A) of title 5, to recover all reasonable costs incurred in processing requests made under section 552 of title 5 for records obtained or created under this chapter or any other Federal law for which responsibility for administration has been delegated to the Commissioner by the Secretary;

(2) retain all fees charged for such requests; and

(3) establish an accounting system and procedures to control receipts and expenditures of fees received under this section.

(b) Use of fees

The Secretary and the Commissioner of Food and Drugs shall not use fees received under this section for any purpose other than funding the processing of requests described in subsection (a)(1) of this section. Such fees shall not be used to reduce the amount of funds made to carry out other provisions of this chapter.

(c) Waiver of fees

Nothing in this section shall supersede the right of a requester to obtain a waiver of fees pursuant to section 552(a)(4)(A) of title 5.

(June 25, 1938, ch. 675, § 711, as added Nov. 28, 1990, Pub. L. 101-635, title II, § 201, 104 Stat. 4584.)

§ 379d. Automation of Food and Drug Administration

(a) In general

The Secretary, acting through the Commissioner of Food and Drugs, shall automate appropriate activities of the Food and Drug Administration to ensure timely review of activities regulated under this chapter.

(b) Authorization of appropriations

There are authorized to be appropriated each fiscal year such sums as are necessary to carry out this section.

(June 25, 1938, ch. 675, § 712, as added Nov. 28, 1990, Pub. L. 101-635, title IV, § 401, 104 Stat. 4585.)

SUBCHAPTER VIII—IMPORTS AND EXPORTS

§ 383. Office of International Relations

(a) There is established in the Department of Health and Human Services an Office of International Relations.

(b) In carrying out the functions of the office under subsection (a) of this section, the Secretary may enter into agreements with foreign countries to facilitate commerce in devices between the United States and such countries consistent with the requirements of this chapter. In such agreements, the Secretary shall encourage the mutual recognition of—

(1) good manufacturing practice regulations promulgated under section 360j(f) of this title, and

(2) other regulations and testing protocols as the Secretary determines to be appropriate.

(June 25, 1938, ch. 675, § 803, as added Nov. 28, 1990, Pub. L. 101-629, § 15(a), 104 Stat. 4525.)

REPORT ON ACTIVITIES OF OFFICE OF INTERNATIONAL RELATIONS

Section 15(b) of Pub. L. 101-629 provided that: "Not later than 2 years after the date of the enactment of this Act [Nov. 28, 1990], the Secretary of Health and Human Services shall prepare and submit to the appropriate committees of Congress a report on the activities of the Office of International Relations under section 803 of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 383], added by subsection (a)."

SUBCHAPTER IX—MISCELLANEOUS

§ 393. Food and Drug Administration

CODIFICATION

Another section 903 of the Federal Food, Drug, and Cosmetic Act is classified to section 394 of this title.

§ 394. Scientific review groups

Without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, the Commissioner of Food and Drugs may—

(1) establish such technical and scientific review groups as are needed to carry out the functions of the Food and Drug Administration (including functions prescribed under this chapter); and

(2) appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

(June 25, 1938, ch. 675, § 903, as added Nov. 28, 1990, Pub. L. 101-635, title III, § 301, 104 Stat. 4584.)

REFERENCES IN TEXT

The provisions of title 5 governing appointments in the competitive service, referred to in text, are classified generally to section 3301 et seq. of Title 5, Government Organization and Employees.

CODIFICATION

Another section 903 of the Federal Food, Drug, and Cosmetic Act is classified to section 393 of this title.

CHAPTER 10—POULTRY AND POULTRY PRODUCTS INSPECTION

CHAPTER REFERRED TO IN OTHER SECTIONS

This chapter is referred to in section 321 of this title; title 7 section 6519.

§ 453. Definitions

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 454, 457, 461, 464, 467b of this title; title 15 sections 2052, 2602.

§ 467b. Seizure and condemnation

(a) Proceedings in rem; libel of information; jurisdiction; disposal by destruction or sale; proceeds into the Treasury; sales restrictions; bonds; court costs and fees, storage, and other expenses against claimants; jury trial; United States as plaintiff

(1) Any poultry product, or any dead, dying, disabled, or diseased poultry, that is being transported in commerce or otherwise subject to this chapter, or is held for sale in the United States after such transportation, and that (A) is or has been processed, sold, transported, or otherwise distributed or offered or received for distribution in violation of this chapter, or (B) is capable of use as human food and is adulterated or misbranded, or (C) in any other way is in violation of this chapter, shall be liable to be proceeded against and seized and condemned, at any time, on a libel of information in any United States district court or other proper court as provided in section 467c of this title within the jurisdiction of which the article or poultry is found.

(2) If the article or poultry is condemned it shall, after entry of the decree, (A) be distributed in accordance with paragraph (5), or (B) be disposed of by destruction or sale as the court may direct and the proceeds, if sold, less the court costs and fees, and storage and other proper expenses, shall be paid into the Treasury of the United States, but the article or poultry shall not be sold contrary to the provisions of this chapter, or the laws of the jurisdiction in which it is sold: *Provided,* That upon the execution and delivery of a good and sufficient bond conditioned that the article or poultry shall not be sold or otherwise disposed of contrary to the provisions of this chapter, or the laws of the jurisdiction in which disposal is made, the court may direct that such article or poultry be delivered to the owner thereof subject to such supervision by authorized representatives of the Secretary as is necessary to insure compliance with the applicable laws.

(3) When a decree of condemnation is entered against the article or poultry and it is released under bond, or destroyed, court costs and fees,